FRESENIUS USA

2008K HEMODIALYSIS SYSTEM

TECHNICIAN'S MANUAL

Part Number 490049 Rev A

FRESENIUS USA
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S E C T I O N I

SPECIFICATIONS

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2008K HEMODIALYSIS MACHINE

Dimensions

Floor space	Approximately 54 cm wide by 63 cm deep
Height	133 cm
Total weight	Approximately 73 kg

Electrical

Power Supply—Main	Single phase AC 120 V ±10% 60 Hz ±3 Hz must be connected to a circuit which is equipped with a hospital grade receptacle and is protected by circuit breaker and ground fault circuit interrupter (GFCI). Resistance from chassis to ground must be < 0.2 ohm.
Power Consumption	Does not exceed 12.5 amps
Fuses	6.3 amp medium blow fuse, 2 each 16 amp double pole rocker switch circuit breaker for heater
External Connections	A. Alarm output normally open and normally closed switch contacts reflecting alarm state. 24 V, 0.2 amp max. B. Alarm input C. External alarm light or traffic light beacon Isolated RS232 and leakage current isolation per UL 544 between the machine and external computer
Heat Dissipation to Room	600 to 700 BTU/hr.

Water

Back Flow Prevention	Integral back flow prevention provided by external vent to atmosphere in water inlet circuit.
Water Pressure	Min 20 psi; max 105 psi
Water Temperature	Min 10 °C; max 25 °C
Quality	AAMI Standard, RD5, 1992
Drain	3 feet maximum height. Must comply with local codes and must maintain a free fall air gap between drain hose and building drain.
Rinsing	Temperature 37° C. Flow rate 620 ml/min. Time between 10 and 60 minutes (internally selectable)

Concentrate Supply

Concentrate Pressure	Max suction height 3 feet Max supplied pressure 2 psi
Dialysate Flow Adjustment Range	Sequential (0)/100/200/300/400/500/600/700/800 ml/ min., selectable in the Dialysis screen;
	Dialysate on/off key
Partial Dialysate Collection	From Drain line, intermittent collection using a 3 Liter PD drain bag as a collection device with a Safe-Lock connector (optional).
Proportional Mixing System	
Acid	Volumetric, selectable:
	1:34
	1:44
	1:35.83
	1:35.1
Acetate	1:34
Adjustment Range	130 to 155 mEq/L Na^+
Bicarbonate	Volumetric, selected with associated acid ratio
	1:27.6
	1:19.1
	1:24.5
	1:28.6

Concentrate Supply (cont.)

Adjustment Range	20 to 40 mEq/L Bicarbonate
Monitoring Conductivity	Temperature compensated conductivity display with automatically set alarm windows ±0.5 mS/cm around calculated conductivity. User can adjust an additional ±0.5mS/cm within this range. Conductivity is based on the concentrates' compositional data entered in the Dialysate screen at the standard temperature of 25°C.
Range of Display	10.0 to 17.0 mS/cm corrected to 25° C. Alarm limits will not go below 13.0 or above 16.0 mS/cm.
Dialysate Heating	35 to 39° C, (selectable in 0.1 ° C steps)
Nominal Value of Temperature Temperature Display	Range 35 to 39° C with alarm limit window automatically adjusted to 2° C above and below set point. Alarm window will not go below 30° or above 41° C. Heater 1.3 kW, electronically controlled.

Heat Disinfection

Temperature	83 ± 8° C at NTC 3
Flow Rate	600 ml/min. Pre-rinse either 7min. @ 600ml/min or 20min. @ 300ml/min. (user selectable)
Time	Between 10 and 60 minutes (internally selectable)

Chemical Disinfection

Temperature	37° C (set point applicable)
Flow Rate	620 ml/min.
Time	Between 10 and 60 minutes (internally selectable)

Blood Pump

Display of flow rate	20 to 600 ml/min, depending on pump segment ID.
Internal diameter of pump segment	2 to 10 mm (0.08" to 0.4")
Tube length	32 cm minimum (12-5/8")
Level adjust	Up only
Power outage use	The pump can be manually operated with a hand crank.

Single Needle System

Two Pump Procedure	With two blood pumps, pressure control system with alternating blood pumps. Alarm after 15 or 30 seconds without an alternation of the pumps.

Heparin Pump

Type of Syringe	10 - 12 ml disposable syringe
Administration Rate	0.1 to 9.9 ml/hr
Monitoring	Monitoring end of stroke
Bolus	From 0.1 to 9.9 ml volume

Monitoring Elements: Blood Circuit

Arterial Pressure Monitor	-300 to +500 mmHg with 3 automatically set time-delayed alarm window limit values (±60, ±80, and ±100 mmHg of actual pressure. (Single Needle ±80mmhg).
Venous Pressure Monitor	-80 to +500 mmHg with 3 fixed window limit values of ±60, ±80, and ±100 mmHg of actual pressure. There is also an asymmetric range initially set to ±80 mmHg which increases the lower limit after 60 seconds. (Single Needle ±80 mmHg).
TMP Monitor	+60 to -520 mmHg with automatically set time delayed window limit values of ±60 (conventional dialysis) and ±40 mmHg (high flux dialysis). Compensation for upward drift.
Level detector	Ultrasonic impulses detect fluid level in the venous drip chamber.
Optical Sensor	Optical transmission used to detect opaque or non-opaque presence in the blood tubing.
Clamp	Closes with any blood alarm to protect patient
Venous Level Adjust	Allows the fluid level in the venous drip chamber to be raised or lowered
Arterial Level Adjust	Allows the fluid level in the arterial drip chamber to be raised
Blood Leak Detector	Two color light source transmitter / sensor with a resolution of: minor ≥ 0.35 ml/min. of blood (hematocrit = 25%) alarm ≥0.45 ml/min. of blood (hematocrit = 25%)

Ultrafiltration Control

Adjustment Range of UF Rate	Volumetric Control, 0-4000 ml/hr. 1000, 2000, 3000, and 4000 ml/hr. internally maximum rate. Adjusted in 10 ml increments.
UF Time	Digital Display (0 – 9:59 hrs.) Selectable in increments of 1 min.
UF Goal	Digital Display (0 to 9,990 ml). Selectable in increments of 10 ml.
UF Profiles	Eight UF profiles (4 preset & 4 user settable) are available for the removal of excess fluid from the patient.
Remaining Time of Dialysis (RTD)	0-9:59 hours auto transfer from UF time, counting down in 1-minute increments. Can adjust manually.
UF Removed Display	Digital display max 9,999 ml counting in 1 ml increments.
Additional Monitoring	Alarm in case of power failure.

Functional Options

Online Clearance	A means of estimating urea clearance during treatment by measuring conductivity responses after brief alterations in dialysate concentration.
Sodium Variation System (SVS)	A means for temporarily increasing the sodium concentration at the beginning of dialysis for patient comfort.
Sodium Variation Profiles	Three preset profiles (step, linear, and exponential) for increasing, then decreasing the sodium concentration in dialysate.
Blood Temperature Monitor (BTM) (Optional)	A means of temperature control for the patient and for evaluating adequacy of access flow by measuring temperature changes in the arterial and venous lines after temporary excursions in the dialysate temperature.
DiaSafe®	A means of filtering the dialysate to reduce bacteriological exposure

Blood Pressure Module

Technique	Measures systolic, diastolic pressures, and heart rate (pulse rate) using oscillometric method. MAP measured.
Cuff Deflation	Interactive computer controlled. Determination for adults requires approximately 25-30 seconds depending on starting point, heart rate and motion artifact.
Cuff Inflation	Typically 5 - 10 seconds from 0-250 mmHg.

Performance Limits

	Pediatric	**Adult**
Cuff Pressure Range	5-220 mmHg	10-325 mmHg
Initial Cuff Inflation	125 mmHg or adjustable	180 mmHg or adjustable
Systolic Determination Range	40-160 mmHg	80-260 mmHg
MAP Determination Range	25-140 mmHg	35-220 mmHg
Diastolic Determination Range	15-120 mmHg	25-200 mmHg
Pulse Rate Determination Range	40-240 BPM	40-180 BPM
Cuff Inflation Rate	5 seconds	5 seconds
Determination Time Normal	Approx. 20 seconds	25-30 seconds
Overpressure Cut Off	220 mmHg	325 mmHg
Transducer Drift	Auto Zeroing	Auto Zeroing
Leakage Rate (Max)	3 mmHg in 4 minutes	3 mmHg in 4 minutes
Pressure Rate Offset	Auto Zeroing	Auto Zeroing
Alarm Preset Values (Internal alarm values preset to provide alarm limits in the event individual values are not entered)	Pediatric/Neonatal	Adult
Systolic	160/80	200/90
MAP	120/70	120/70
Diastolic	100/60	110/50
Pulse	120/50	120/50
Inflation Pressure	Auto	Auto

PRODUCT IMPROVEMENT POLICY

The Fresenius 2008K Dialysis System was designed and built to comply with these specifications. It is the intention of Fresenius USA to continuously do product development which may result in modifications and improvements to specifications or equipment produced in the future. Such product improvements shall not incur any obligation to make similar changes or improvements to equipment previously produced. These changes or improvements may or may not be applicable or usable with previously produced equipment. Where possible, improvements will be made available at reasonable prices. Any such improvements shall not be construed as corrections of any deficiency.

In order to properly calibrate and maintain the 2008K Dialysis System, the documentation being used must be up to date. The current revision of a document can be obtained through the Fresenius Customer Service department at 800-227-2572.

S E C T I O N I I

GENERAL WARNINGS & CAUTIONS

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Precautions:

Federal (USA) law restricts this device to sale only by or on the order of a physician. Frequency, duration, and parameters are to be determined by the prescribing physician.

Warnings:

The electrical source must be single phase, three conductor type provided with a hospital grade receptacle and a ground fault interrupter at 120 volts, 60 Hz. The proper polarity and ground integrity must be initially checked and thereafter maintained. Failure to do so may result in electrical shock to the operator or patient.

Shock hazard. Do not remove covers. Refer servicing to qualified personnel.

Replace fuses only with the same type and rating.

Hemolysis of blood in the dialyzer will occur should the dialysate fluid exceed a temperature of 42°C (107°F). Dialysate temperatures must be maintained below this level. Do not return hemolyzed blood to the patient.

Check the conductivity and pH of the dialysate solution with an independent device before initiating dialysis.

Indications:

Hemodialysis is indicated for patients with acute or chronic renal failure, when conservative therapy is judged to be inadequate.

Contraindications:

There are no absolute contraindications to hemodialysis, but the passing of a patient's blood through an extracorporeal circuit may require anticoagulation to prevent blood clotting. In addition, the parameters of dialysis should be optimized to avoid discomfort to the patient. Many patients are taking medicinal therapy prescribed by their physicians. Due to the dialysis treatment, some of the medication may be removed from the patient's blood thereby lowering the therapeutic level in the blood. Therefore, the prescribing physician should determine the appropriate dosage of medicine to avoid loss of the desired medicinal response in the patient.

Side Effects:

Dialysis therapy occasionally causes hypovolemia, hypervolemia, hypertension, hypotension, headache, nausea, or cramping in some patients. These symptoms are thought to occur if the patient's blood volume or electrolyte balance is not maintained within acceptable limits. Proper control of all elements of dialysis may prevent or control these physiological reactions.

Pyrogenic reactions may occur which can result in patient injury. Generally it is thought that this may be controlled by maintaining the dialysate solution within the chemical and bacteriologic limits specified in the AAMI (1982) standards for water for dialysis. A regular program for disinfection and testing of the water treatment system, piping, inlet lines, filters, and the central delivery system be established and followed. This program will vary from facility to facility.

All blood connections must be made using aseptic technique.

All tubes and connections must be checked for security and kinking to prevent loss of blood or entry of air into the extracorporeal circuit or errors in the ultrafiltration control system.

The patient's blood pressure and general physical status must be closely monitored during dialysis in order to initiate appropriate remedial measures or therapy. Of particular importance is the control of the patient's serum potassium level as well as the patient's blood clotting time.

Warning: Failure to install, operate, and maintain this equipment according to manufacturers' instructions may cause patient injury.

Warning: Calibrations and maintenance procedures must not be carried out while a patient is connected to the bedside station. If possible, it is a good practice to remove the machine from the treatment area when the machine is being serviced. The machine should be labeled with it's status so that is not accidentally used while still undergoing service operations.

Caution: Calibration procedures should be against either primary standards or against standards that are regularly calibrated in a program where the basic standards are traceable to the National Institute of Standards and Technology (National Bureau of Standards).

Warning: Any machine filled with a chemical for cleaning or disinfection must be clearly labeled by the operator. The label should indicate what the chemical is and that rinsing and testing is required before clinical use of the dialysate delivery machine.

Warning: At the end of the rinsing process, after chemical disinfection, the drain water must be tested for disinfectant residual.

Warning: The 2008K Hemodialysis machine is compatible with a number of venous lines. The level detection circuit must be calibrated for the model line you are using. During calibration the filter inside the drip chamber must be below the sensor heads. Refer to the calibration instructions. In addition, verify that the venous clamp is capable of fully occluding the line.

Warning: During the priming procedure verify that an air alarm causes the blood pump to stop and the venous clamp to close and the line to be clamped.

Caution: An uncontaminated transducer protector should be placed on all the air connections from the drip chambers to the machine pressure connections. This will prevent contamination of the machine and filter air which enters the chambers through the monitor lines.

Caution: It is absolutely necessary that the dialyzer couplings close tightly so that, with negative pressure on the dialysate compartment, air cannot leak into the dialysate circuit or if under positive pressure, fluid cannot leak out, adding to the intended ultrafiltration. This condition is of special importance with non - standardized dialyzer connections.

S E C T I O N I I I

HYDRAULIC DESCRIPTION

DESCRIPTION OF THE HYDRAULIC COMPONENTS

All valves and motors are supplied with 24V DC; the heater is supplied with 120V AC 60Hz; thermistors, float switch, blood leak detector, pressure sensors and reed switches with 12V DC; conductivity cell and level sensor with 12V AC at high frequencies;

Inlet filter screen
Prevents the 2008K components from being obstructed (mounted in the inlet water line of the 2008K).

Water inlet regulator
Limiting the inlet water pressure.

Balancing chamber
The most important component for volumetric dialysate balancing; two spherical chambers (30m1 each); 8 solenoid valves; two membranes reliable and proven hydraulic component from A2008C/D/E/H series; guarantees accurate fluid balancing.

Hydroblock
Consists of heater; including valve "39" and an orifice to provide sufficient volume to deaerate the water; separates the air from the water and provides mounting for the loading pressure valve; control NTC 2 (temperature sensor for temperature control circuit);
function: warming water; provides air gap and a level sensor to maintain the water level.

Monitoring NTC 3
Function: independent temperature sensor for temperature monitoring.

Flow indicator
Optical flow indication and gross flow measurement.

Dialyzer valves V24, V25, and bypass valve V26
Bypasses (V24 closed, V25 and V26 open) the dialyzer and prevents exposure of the patient to improper dialyzing fluid (temperature or conductivity alarm); the dialyzer can be isolated (V24 and V25 closed, V26 open; i.e. for online pressure holding test or TMP alarm.

Dialysate line safety interlock
2 switches for dialysate lines;
1 switch for interlock cover;
provides additional safety against inadvertently rinsing or disinfection;
defines dialyzer emptying program.

Dialyzer filter
Prevents hydraulic components from being obstructed; mounted outside 2008K; easy to service.

Pressure transducer
Pressure transducer for dialysate pressure measurement; used also as a sensor for the pressure holding test.

Blood leak detector
Color sensitive blood leak detector (temperature compensated), is able to distinguish between opaque layers in the cell and real presence of blood in the dialyzing fluid.

Secondary air separator
Guarantees precise weight removal; device contains fluid level detector, air separation volume and valve V43.

Chamber Full Switch
Senses pressure peak to switch the balance chamber.

Flow pump
DC motor driven gear pump;
function: filling of the balancing chamber.

Deaeration pump
Provides deaeration and loading pressure.

Heat exchanger
Preheats inlet water.

Conductivity cell
Measures conductivity.

UF pump
Responsible for fluid removal

Concentrate pump
Delivers acetate or acid concentrate; proportioned by the microprocessor according to settings in the DIALYSATE COMPOSITION SCREEN.

Bicarbonate pump
Delivers bicarbonate to the mixing chamber; proportioned by the microprocessor according to settings in the DIALYSATE COMPOSITION SCREEN.

Recirculation valve V29
Allows fluid to the drain to be diverted into the hydroblock; used in heat disinfect to heat up faster and to conserve energy.

HYDRAULIC OPERATION

1. Time constants

The overlap time (delay time) of the balancing chamber valves is always 50 ms. This time is included in the switching time of the balance chamber (ie. switching time is 6.00 seconds means 5.95 sec. fill time plus 50 ms delay time).

Time constants of the balance chamber.

Flow rate 100 ml/min t = 18.0 s ± 10%
Flow rate 200 ml/min t = 9.0 s ± 10%
Flow rate 300 ml/min t = 6.0 s ± 10%
Flow rate 400 ml/min t = 4.5 s ± 10%
Flow rate 500 ml/min t = 3.6 s ± 10%
Flow rate 600 ml/min t = 3.0 s ± 10%
Flow rate 700 ml/min t = 2.57 s ± 10%
Flow rate 800 ml/min t = 2.25 s ± 10%

2. Rinse

Rinse can only be started if the concentrate and bicarbonate connectors are in their rinse ports, the dialyzer couplings are connected to the shunt and the shunt door is closed.

At the beginning of rinse the hydraulics are flushed. Valves V30, V31, V32, V33, V34, V35, V36, V37, V38, V24, V25, V39, the deaeration pump and the flow pump on and the concentrate pumps run maximum stroke volume, V26 opens and V24/V25 closes. Every 1.45 seconds valve 30 closes and valve 29 opens.

Every cycle the UF pump runs at 3000 ml/h, V43 alternates on/off, and the concentrate and bicarbonate pump stroke every balancing chamber cycle. This pattern assures that all the various parts of the hydraulics get adequately rinsed.

The rinse program lasts until it is stopped by the timer counting to 0 or by the operator. The set time and the remaining time on rinse are displayed on the screen.

3. Mandatory Rinse

Mandatory rinse has to be performed always after a CHEMICAL disinfection and/or ACID CLEAN. The user is informed by a message in the status line on the screen. The only difference between mandatory rinse and a regular rinse program is, that the mandatory rinse has to run for a predefined time and cannot be terminated.

Mandatory rinse can only be started if the concentrate and bicarbonate connectors are in their rinse ports, the dialyzer couplings are connected to the shunt and the shunt door is closed.

During mandatory rinse the set time and the remaining time are displayed. If the remaining time is zero the machine stops and displays a message "PRESS CONFIRM".

NOTE: If the machine was turned off or connectors are pulled during mandatory rinse before the needed time was over the machine comes up with mandatory rinse again after power on.

4. Chemical Disinfection

There are two different chemical disinfection procedures.

A. Chemical/Rinse (followed immediately by a mandatory rinse)

B. Chemical/Dwell (mandatory rinse may be done at a later time or date)

Chemical disinfection can only be started if the concentrate and bicarbonate connectors are in their rinse ports, the dialyzer couplings are connected to the shunt and the shunt door is closed.

5. Heat disinfect

Heat disinfect can only be started if the concentrate and bicarbonate connectors are in their rinse ports, the dialyzer couplings are connected to the shunt and the shunt door is closed.

If the machine has performed any program other than rinse or heat disinfect before, the heat disinfect program always starts with a pre-rinse for 7 minutes (or 20 minutes if "EXT. PRE RINSE" is selected in the OPTIONS of SERVICE MODE) to rinse out concentrate or any disinfectant. This is not displayed on the screen.

After pre-rinse, the machine starts running in recirculation mode (V29 open and V30 closed). When the water temperature reaches 80°C, the timer starts decrementing until it reaches 0 and the cycle is finishes. The set time and the time left are displayed on the screen. If the predefined time has elapsed, the machine turns off all pumps and valves and displays the message "FINISHED" in the status line or, if set, the machine will power off when heat disinfection finishes.

NOTE: The heat disinfection time is selectable by the user in the OPTIONS of SERVICE MODE.

6. Flow off

After the flow has been turned off from the front panel, the heater is turned off and the deaeration pump will turn off after one minute.

7. No program mode (opening screen)

In "no program state" everything is off. Alarms are not active nor displayed. If blood is sensed there will be an audible alarm and a message in the display. The heater is disabled.

8. Fill mode

Flow rate is 300 (about 4 volts to the flow pump pressure lower than loading pressure, because V43 is open and the fresh filled chamber may be partially emptied by dialysate being pressed back by the flow pump). The balance chamber will be switched by the CFS (chamber full switch) sensor (threshold lower than loading pressure). As long as the deaeration pump is filling the BC, the CFS pressure should be fairly low. If both chambers are filled, the pressure will peak (just like in regular dialysis). This big pressure peak is used to switch the BC. This insures that the correct proportioning of the concentrates is given. The level sensor #6 is only checked at the end of the cycle. If there is still air in the air separator, the next cycle is performed. If not, the machine will go on with dialysis. If the fill mode occurs with the venous pressure >50 mmHg and/or blood is sensed (patient is connected to the machine) valves 24 and 25 are on and valve 26 is off during fill mode. UF is stopped during fill. If fill is running for more than 10 chamber cycles (300 ml) there will be a permanent fill alarm and a displayed message.

Note: Fill mode starts and ends always after a complete cycle.

Dialysis cycle one is followed by fill cycle two.
Dialysis cycle two is followed by fill cycle one.
Fill cycle one is followed by dialysis cycle two.
Fill cycle two is followed by dialysis cycle one.

9. Flow alarm

Flow alarm will occur if:

a. The float switch opens valve 41, and the water level is not up within the next 14 sec. All balance chamber valves shut off, heater is off until the sensor detects water ("NO WATER" message is displayed).

b. If the float switch does not detect a low level within 2.5 sec. after the balance chamber did cycle ("INLET FLOW ERROR" message is displayed). Exception is recirculation.

Heater off

c. The CFS (chamber full switch) does not switch the balance chamber for 10 sec. Exception is flow off and non program state. Heater off ("FLOW ERROR" is displayed).

d. The CFS switches the chamber faster than 1.8 sec. Heater off ("HIGH FLOW ERROR" is displayed).

DISTRIBUTION BOARD LAYOUT

Definition of component function

x2. Temperature control thermistor (CON-NTC)
Controls temperature in the heater chamber.

x3. Temperature monitor thermistor (MON-NTC)
Monitors temperature in the conductivity cell block, bypass is initiated when temperature is out of limits.

x4. Not Used

x5. Level sensor (float) in hydroblock (FLOAT-SW)
Controls water inlet valve 41 and it's signal is used to detect flow problems.

x6. Air sensor in air separator chamber (AIR-SEN)
Detects air coming from the dialyzer and is used to trigger the fill mode.

x7. Conductivity cell (COND)
Monitors the conductivity before the dialyzer, bypass is initiated when conductivity is out of limits.

x8. Blood leak detector (BLOOD LEAK)
Detects blood in the return line of the dialyzer and triggers the minor blood leak warning and the blood leak alarm.

x9. Dialysate pressure transducer (P-DIAL)
Measures the dialysate pressure. This value is used to calculate the TMP.

x10. Chamber full switch (CFS)
The pressure spike seen by this transducer is used to switch the balance chamber. The time between pulses and the selected flow rate will set the voltage to the flow pump. It is intended to limit the height of the pressure spike to a certain value (a little higher than the loading pressure at all pump speeds).

x11. Reed switch for concentrate connector (CONC-SW)
Disables the concentrate pump.

x12. Reed switch for bicarbonate connector (BIC-SW)
Disables the bicarbonate pump.

Definition of component function (cont.)

x13. Post Conductivity Cell (COND-POS)
Monitors the conductivity after the dialyzer. Used during Online Clearance (OLC) testing.

x44. Post Temperature thermister (NTC-POST)
Monitors temperature in the post conductivity cell block. Used during Online Clearance (OLC) testing.

x14. Not Used

x15. Not Used

x16. Concentrate pump with end of stroke sensor (CONC-P)
Delivers acetate or acid concentrate into the water inlet chamber. It will fully discharge it's volume and refill on every switching of the balance chamber.

x17. Bicarbonate pump with end of stroke sensor (BIC-P)
If enabled (see # 12), this pump delivers bicarbonate into the recirculation chamber. It will fully discharge its volume and refill (possibly twice depending on the volume needed for the concentrate selected) on every switching of the balance chamber.

x18. Not Used

x19. Not Used

x20. Deaeration pump (DEGAS-P)
Is calibrated in software, using a pressure gauge on the inlet of the pump.
The pressure is set to - 24 inches of Hg (-610 mmHg).

x21. Flow pump (FLOW-P)
It is controlled by software. The pump speed depends on the flow rate selected.

x22. UF pump (UF-P)
The volume is calibrated to 1ml per stroke. The frequency of strokes is controlled by software.

x23. Not Used

x24. Dialyzer valve 1 (DIAL-V1)
Valve 24

x25. Dialyzer valve 2 (DIAL-V2)
Valve 25

x26. Bypass valve (BYPAS-V)
Valve 26

Definition of component function (cont.)

x27 Inlet Water Valve (IN-V)
Valve 41
This valve is controlled via level sensor # 5.

x28. Not Used

x29. Recirculation valve (REC-V)
Valve 29

x30. Drain valve (DRAIN-V)
Valve 30

x31 Balance chamber valve 31.

x32. Balance chamber valve 32.

x33. Balance chamber valve 33.

x34. Balance chamber valve 34.

x35. Balance chamber valve 35.

x36. Balance chamber valve 36.

x37. Balance chamber valve 37.

x38. Balance chamber valve 38.

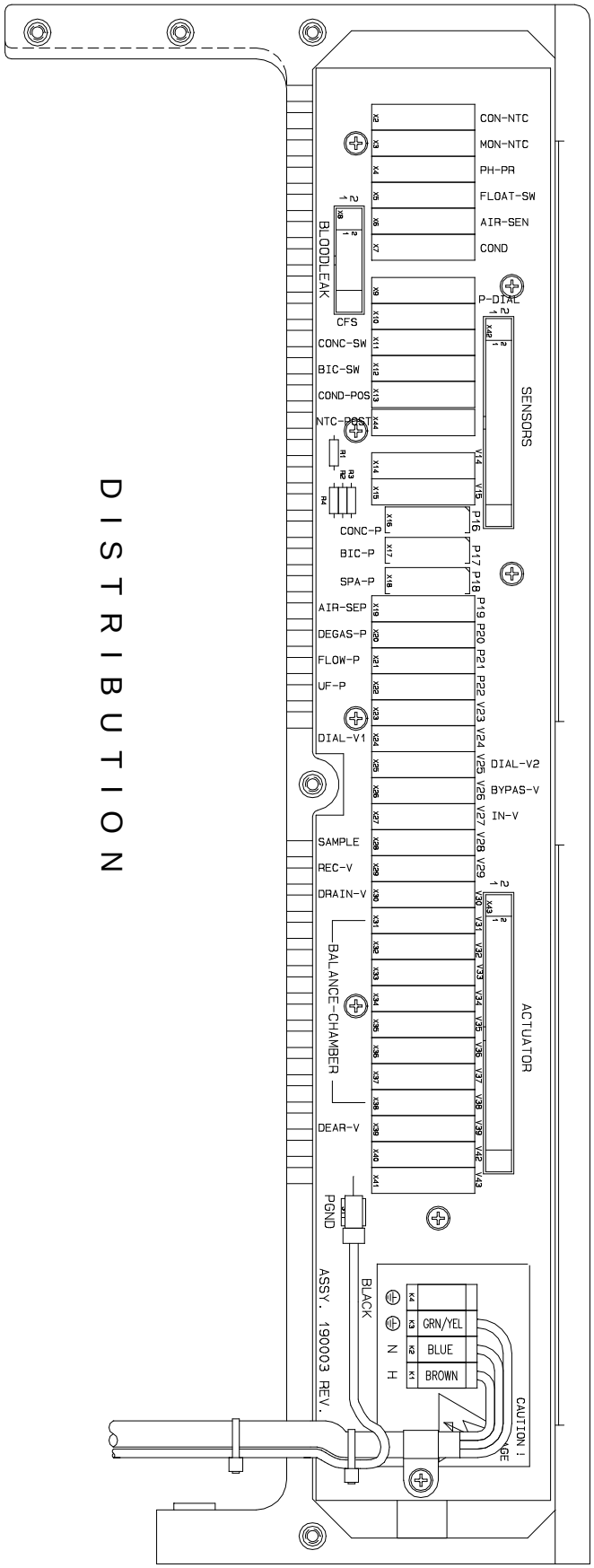
x39. Bypass valve for deaeration orifice - valve 39.
This valve is on in all cleaning cycles.

x40 Not Used

x41. Vent valve for air separator - valve 43.

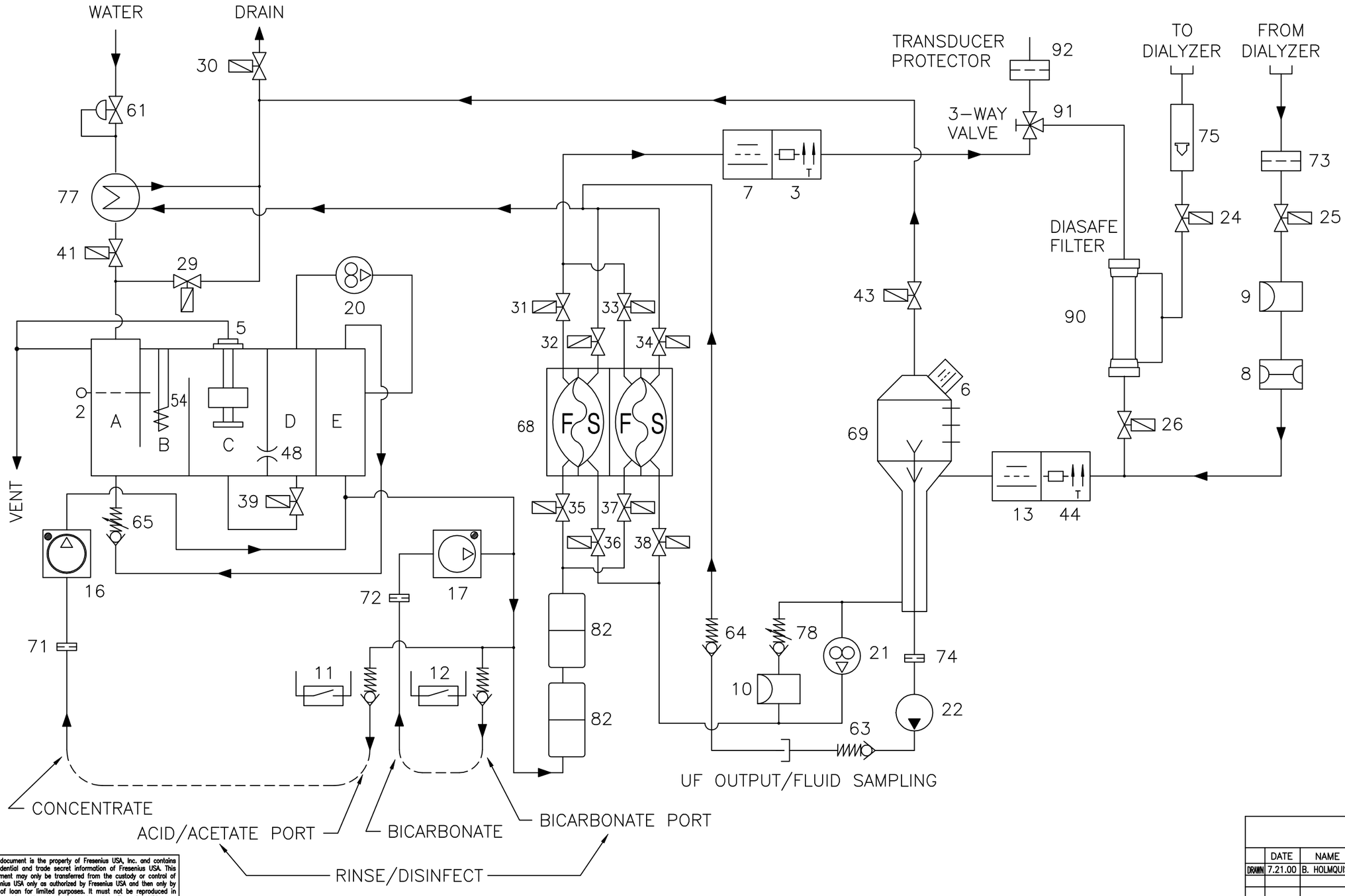
x42 Ribbon cable connection from sensor board.

x43 Ribbon cable connection from actuator board.


DISTRIBUTION
CON-NTC
MON-NTC
PH-PR
FLOAT-SW
AIR-SEN
COND
BLOODLEAK
CFS
P-DIAL
SENSORS
CONC-SW
BIC-SW
COND-POS
NTC-POST
CONC-P
BIC-P
SPA-P
AIR-SEP
DEGAS-P
FLOW-P
UF-P
DIAL-V1
DIAL-V2
BYPAS-V
IN-V
SAMPLE
REC-V
DRAIN-V
BALANCE-CHAMBER
DEAR-V
ACTUATOR
PGND
BLACK
GRN/YEL
BLUE
BROWN
N
H
ASSY. 190003 REV.
CAUTION !

HYDRAULICS: FRESENIUS 2008K

REV	ECO #	BY	DATE	CHK	REVISION
A	7222	BH	7.21.00	JEF	RELEASE



COMPONENT LIST FOR FLOW DIAGRAM 2008K

2. TEMPERATURE CONTROL THERMISTOR
3. TEMPERATURE MONITOR THERMISTOR
5. FLOAT SWITCH
6. AIR SENSOR IN AIR SEPARATOR CHAMBER.
7. CONDUCTIVITY CELL
8. BLOOD LEAK DETECTOR
9. DIALYSATE PRESSURE TRANSDUCER
10. CHAMBER FULL SWITCH
11. REED SWITCH CONCENTRATE WAND
12. REED SWITCH BICARBONATE WAND
13. POST CONDUCTIVITY CELL
16. CONCENTRATE PUMP
17. BICARBONATE PUMP
20. DEAERATION PUMP
21. FLOW PUMP
22. UF PUMP
24. DIALYZER VALVE 1
25. DIALYZER VALVE 2
26. BYPASS VALVE
29. RECIRCULATION VALVE
30. DRAIN VALVE
31. BALANCE CHAMBER VALVE
32. BALANCE CHAMBER VALVE
33. BALANCE CHAMBER VALVE
34. BALANCE CHAMBER VALVE
35. BALANCE CHAMBER VALVE
36. BALANCE CHAMBER VALVE
37. BALANCE CHAMBER VALVE
38. BALANCE CHAMBER VALVE
39. BYPASS VALVE FOR DEAERATION ORIFICE
41. WATER INLET VALVE
43. VENT VALVE FOR AIR SEPARATION CHAMBER
44. POST TEMPERATURE THERMISTOR
48. DEAERATION ORIFICE
54. HEATER
61. WATER INLET PRESSURE REGULATOR
63. CHECK VALVE FROM UF PUMP TO SAMPLE PORT
64. CHECK VALVE FROM SAMPLE PORT TO DRAIN
65. LOADING PRESSURE VALVE
69. AIR SEPARATION CHAMBER
71. ACID/ACETATE FILTER
72. BICARBONATE FILTER
73. FROM DIALYZER LINE FILTER
74. UF PUMP FILTER
75. DIALYSATE LINE FLOW INDICATOR
77. HEAT EXCHANGER
78. FLOW PUMP PRESSURE RELIEF VALVE
82. MIXING CHAMBER
90. DIASAFE FILTER
91. 3–WAY VALVE
92. TRANSDUCER PROTECTOR

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	DATE	NAME
DRAWN	7.21.00	B. HOLMQUIST

MATERIAL

2008K HYDRAULIC FLOW DIAGRAM

SCALE NONE

FRESENIUS

700072

REV A

O:\ACAD\7\700072.DWG

S E C T I O N I V

ELECTRONIC CIRCUIT DESCRIPTION

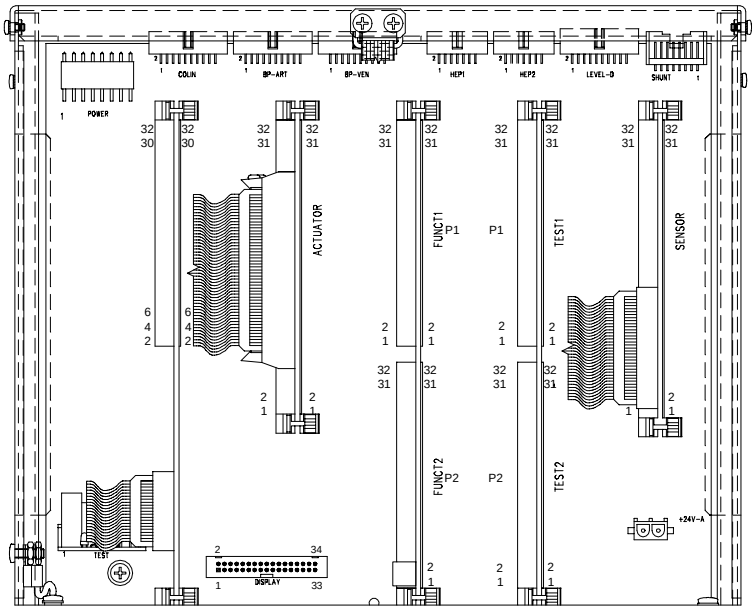
BRIEF DESCRIPTION & LOCATION OF 2008K ELECTRONICS

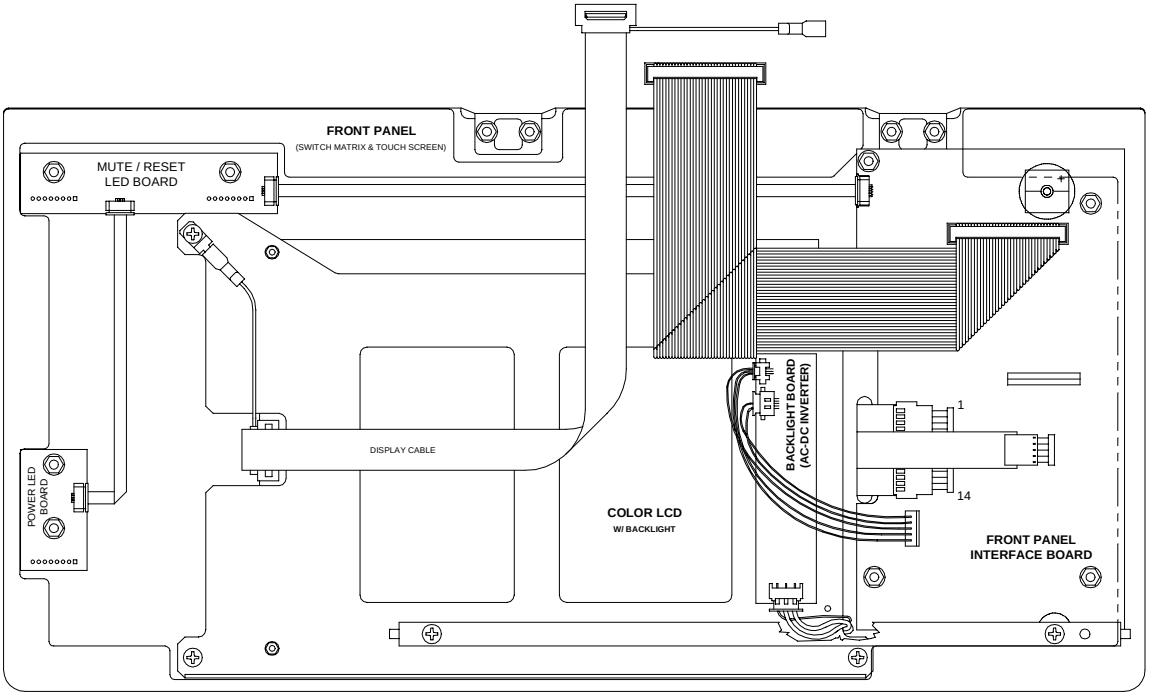
BOARD	LOCATION	DESCRIPTION
Power Control	Power Supply	Magnetic resonant power supply, 24V, heater supply, stand-by power supply and heater control circuit.
Touch Screen	Front Panel	Integral part of the front panel that handles the user inputs to the color LCD display.
Color LCD Display assembly	Front Panel	Color LCD display with integral backlight
Front Panel Interface board	Front Panel	Interprets the touch screen and key matrix. Interfaces all LED's on the front panel with the functional board. Contains all LED's except for the POWER, Mute, & RESET lights.
Mute/Reset LED board	Front Panel	Contains the LED's for the red Mute light and the green RESET light. Interfaces with the front panel interface board and has a connection for the Power LED board.
Power LED board	Front Panel	Contains the LED for the green POWER light. Interfaces with the front panel interface board through the Mute/Reset LED board.
Mother board	Card Cage	Distribution board for card cage boards
-12 Volt Inverter board	Card Cage	-12v, Blood pressure module
Power Logic board	Card Cage	+5v, +12v, DC to DC converters
Actuator board	Card Cage	Drivers and control for valves, pumps and monitors board interface for sensor and secondary monitor (independent A/D converter) circuits
Functional board	Card Cage	Functional processor; operating logic control and control of displays
Test board	Card Cage	Monitor for functional board watchdog, test signal generator
Sensor board	Card Cage	Amplifiers for pressure transducer, temperature, conductivity and other sensors, ADC's
Distribution board	Hydraulic	Interconnection of hydraulic components to the card cage
Blood Leak Detector	Hydraulic	Potted SMD board, BLD electronics

For troubleshooting purposes, a complete set of 2008K Electronic Block Diagrams (P/N 290174) is located in the "Troubleshooting" section. They illustrate the interconnectivity of the card cage, modules, and hydraulics.

2008K BOARD LAYOUT

CARD CAGE
LEFT TO RIGHT:
POWER LOGIC BOARD
ACTUATOR BOARD
FUNCTIONAL BOARD
TEST BOARD
SENSOR BOARD





REAR PANEL OPERATING ELEMENTS

LOUDSPEAKER - The machine can make two kinds of sounds: a warning sound, and an alarm sound. The two sounds are quite distinct; the first one is used for lower priority alarms, and the second for more important alarms.

SERIAL INTERFACE - standard RS 232 serial interface connector; hard wired, used for display terminal connection.

POWER FAILURE ALARM - 9V alkaline battery for main power failure

HYDRAULIC CONNECTION PANEL

TO DIALYZER - tubing to dialyzer (blue dialyzer quick connector)

FROM DIALYZER - tubing from dialyzer (red dialyzer quick connector)

WATER INLET - hose for water inlet

TO DRAIN - outlet hose to drain

GROUND - fixing screw for potential equalization

POWER SUPPLY PANEL

HEATER BREAKER - circuit breaker for heater element

MAIN BREAKER - main line voltage switch

POWER CABLE - cable connection to wall socket

S E C T I O N V

MODULES DESCRIPTION

ARTERIAL BLOOD PUMP MODULE

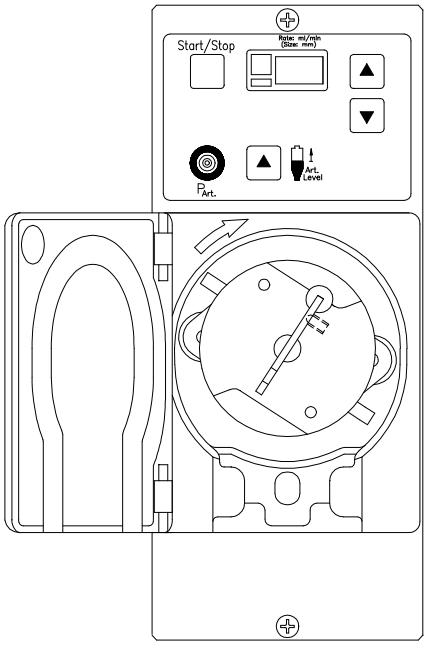
The blood pump draws blood from the patient and pumps it to the dialyzer and back to the patient in a closed circuit. As the pump rotor rotates, twin rollers squeeze the pump segment, pulling and pushing the blood through the blood pump segment. The spring force of the twin rollers is designed in such a way, that the delivery pressure with the prescribed blood line system is limited to 2 bar (30 psi), which rules out ruptures of the blood lines from kinking or clogging. In the cold state, i.e. in the preparation phase, the delivery pressure is even less and because of the bloodline tolerances, the pump may not self prime with air. The blood pump segment is held in place by a spring-loaded device located below the pump rotor. The pump rotor is removable for cleaning.

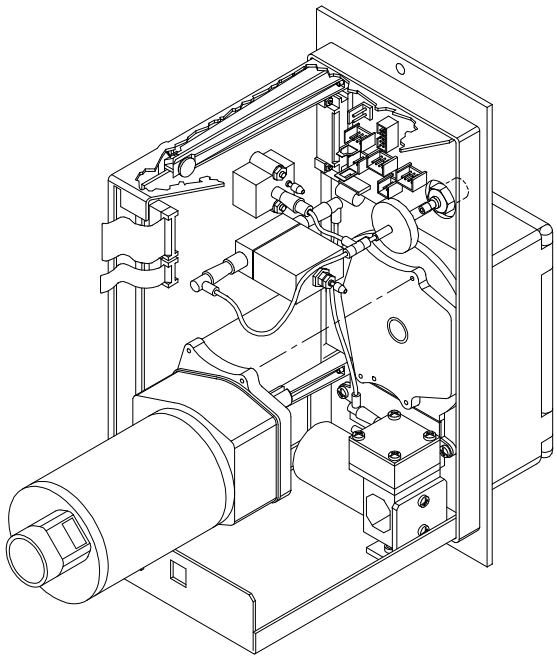
For reasons of personnel safety, the blood pump will run only when the door is closed. The speed of the pump can be adjusted using the arrow keys on the blood pump. The blood pump can be stopped by pressing the Start/Stop key or by opening the blood pump door. When the door is open, the diameter of the pump segment is shown in the display window.

The arterial pressure monitor port is located above the pump housing. Utilizing the arterial pressure port and a small air pump the arterial chamber level can be raised. By pressing the Level Adjust key, the air pump runs and removes air from the arterial chamber allowing the level to rise. Due to the risk of introducing air into the closed blood circuit, the air pump only removes air to raise the chamber level and cannot be used to lower it.

If it should become necessary, because of power failure or line problem, the pump can be operated manually (in clockwise direction) with a separate hand crank attached to the rear panel of the machine.

The module is attached to the machine cabinet with two screws. The electrical connection to the card cage can be removed once the rear panel has been removed.





Note: Refer to Chapter 6 - Alarms and Troubleshooting section of the 2008K Operator's Manual (P/N 490042) for a complete list of alarm codes (A.xx) and error codes (E.xx).

Blood Pump Operating and Indicating Elements

Item 1: Delivery rate selectors (up and down keys).
Using the delivery rate selectors, the delivery rate of the pump can be set to between 20 ml/min and 600 ml/min depending on pump segment ID.

Item 2: Blood pump segment tubing diameter selection.
The display of the segment diameter can be adjusted from 2 to 10 mm (0.08" to 0.4"). The segment diameter is displayed when the door is opened.

Item 3: Delivery rate display
3 digit LED display Resolution: 10 ml.
Red stoppage alarm display lights up if the rotor stops for 15 seconds (optional 30 seconds) when blood pump is switched on.

Item 4: Alarm and Error codes
A set of alarm codes (A.xx) and error codes (E.xx) will be displayed to inform the operator of a problem with the blood pump. A complete list of these codes along with cause and solution can be found in Chapter 6 – Alarms and Troubleshooting section of the 2008K Operator's Manual (P/N 490042).

Item 5: Blood pump door.
Switches the blood pump off when opened.

Item 6: Start/Stop key.
Starts and Stops the rotor when pressed.

Item 7: Arterial Pressure port "P ART"
Luer lock.

Item 8: Level Adjust key.
Raises the arterial chamber when pressed.

Note: Refer to the "Specifications" section for the blood pump specifications.

LEVEL DETECTOR / VENOUS CLAMP MODULE

The module contains the holder for the venous drip chamber with air sensor, the connection for the venous return pressure and the venous clamp with optical blood/saline detector.

The venous drip chamber is pressed into the holder by the cover and is thereby slightly deformed. This is the only way to ensure proper function.

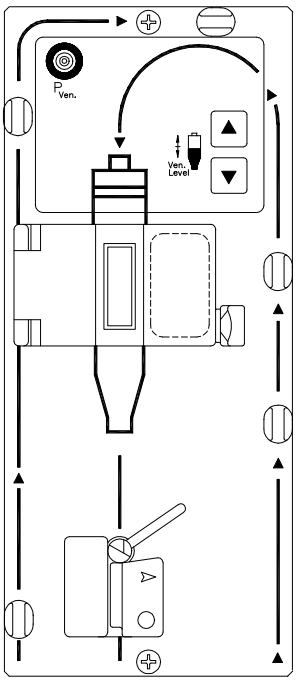
WARNING: The electronic adjustment procedure (see section "Calibration and Installation Procedures" for details) has to be performed for each drip chamber make and model. Make sure the filter in the drip chamber is below the sensor heads during the entire calibration procedure.

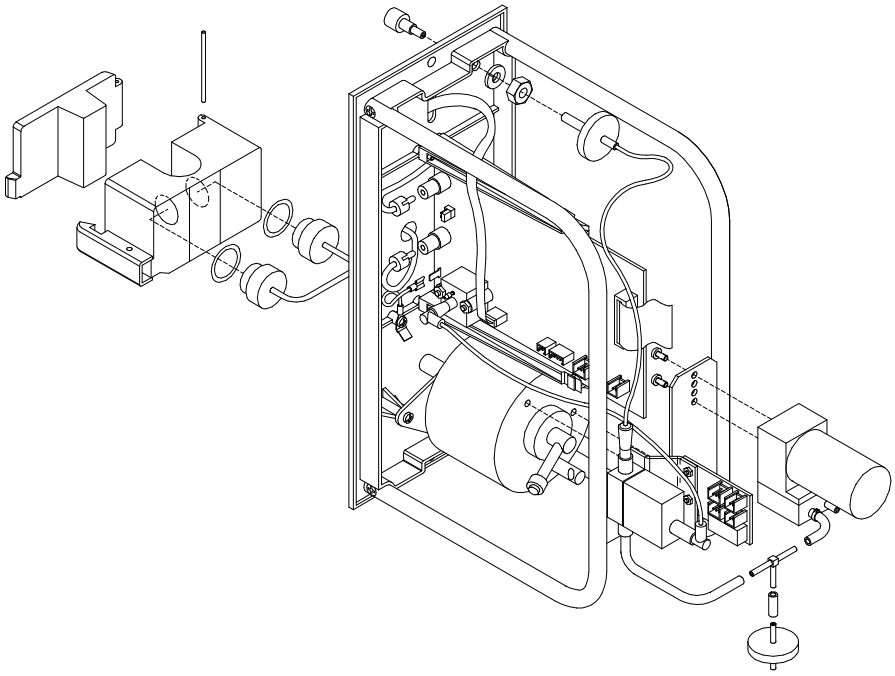
The venous drip chamber is connected via a filter to the pressure connection. The venous return pressure is indicated in the monitor.

The vent valve is located in the pressure line inside the plug-in module. The vent valve is controlled by the override automatic priming logic.

The venous clamp blocks off the extracorporeal circulation from the patient in the event of an alarm. The optical detector in the clamp holder detects blood in the tube system. Provided saline solution or air are present in the tube, the audible alarm, venous return pressure alarm and staff call are suppressed.

The module is attached to the machine cabinet with two screws. The electrical connection to the card cage can be removed once the rear panel has been removed.





Note: Refer to the "Specifications" section for the level detector specifications.

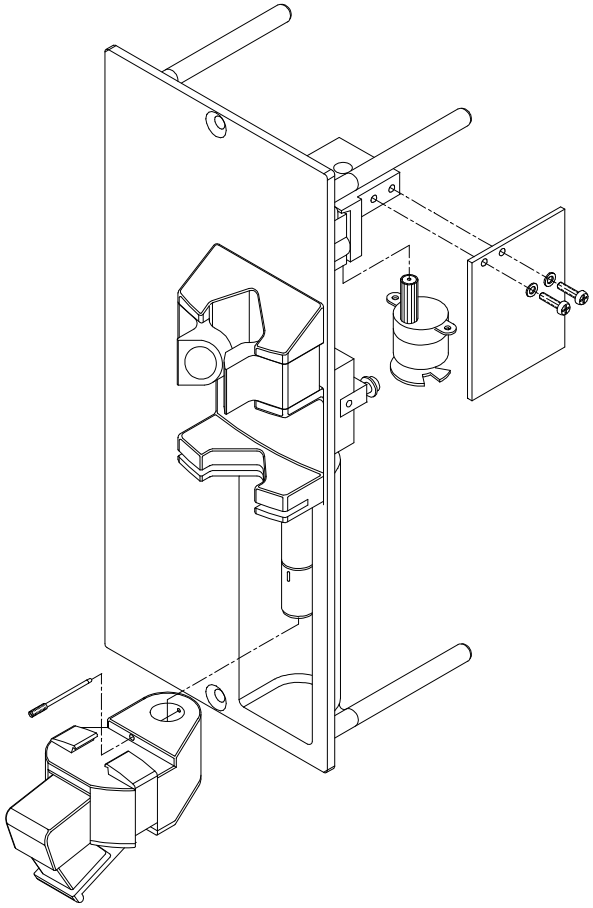
HEPARIN PUMP PLUG-IN MODULE

The heparin pump provides a means of injecting heparin into the blood circuit gradually over the course of the treatment or as a bolus. The pump works in conjunction with the Heparin screen where the following parameters can be set:

- size and type of syringe
- infusion rate
- infusion time
- bolus amount

The module consists of a syringe holder and a carriage to push the syringe plunger at a metered rate.

The module is attached to the machine cabinet with two screws. The electrical connection to the card cage can be removed once the rear panel has been removed.



Note: Refer to the "Specifications" section for the heparin pump specifications.

BLOOD PRESSURE MODULE

The blood pressure module utilizes an oscillometric method of obtaining an error free non-invasive blood pressure measurement. The module contains an inflation pump, pressure relief valve, pressure transducer and circuitry to measure systolic, diastolic pressures and heart rate (pulse rate). From the systolic and diastolic pressures the mean Arterial Pressure (MAP) can be calculated.

The blood pressure module works in conjunction with the Blood Pressure screen where the following parameters can be set:

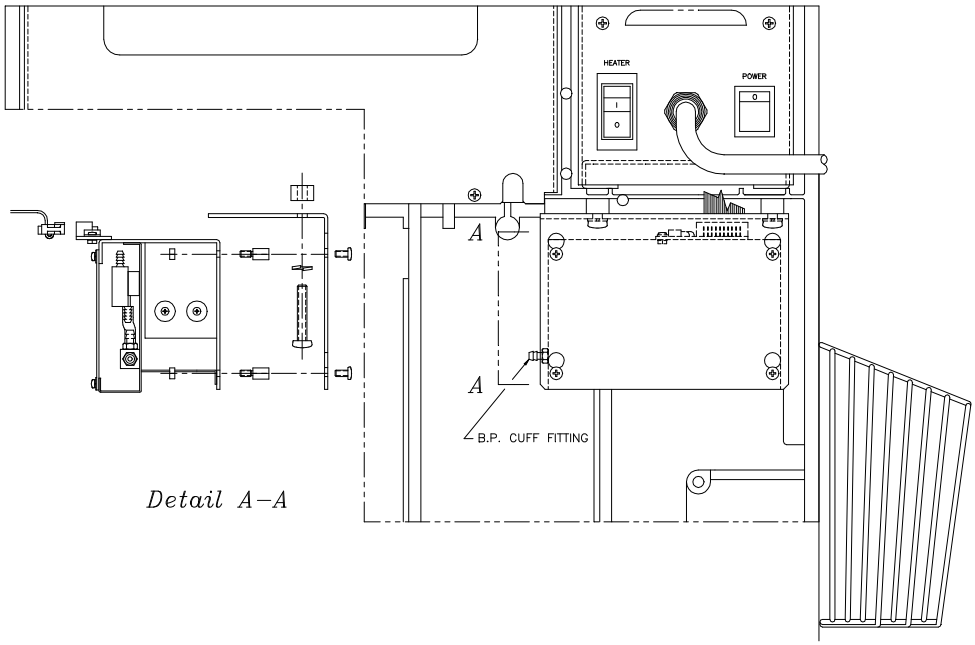
Blood Pressure Alarm Limits

- Upper & Lower Systolic pressures
- Upper & Lower Diastolic pressures
- Upper & Lower Pulse rates

Blood Pressure Settings

- Inflation Pressure
- Interval between blood pressure readings

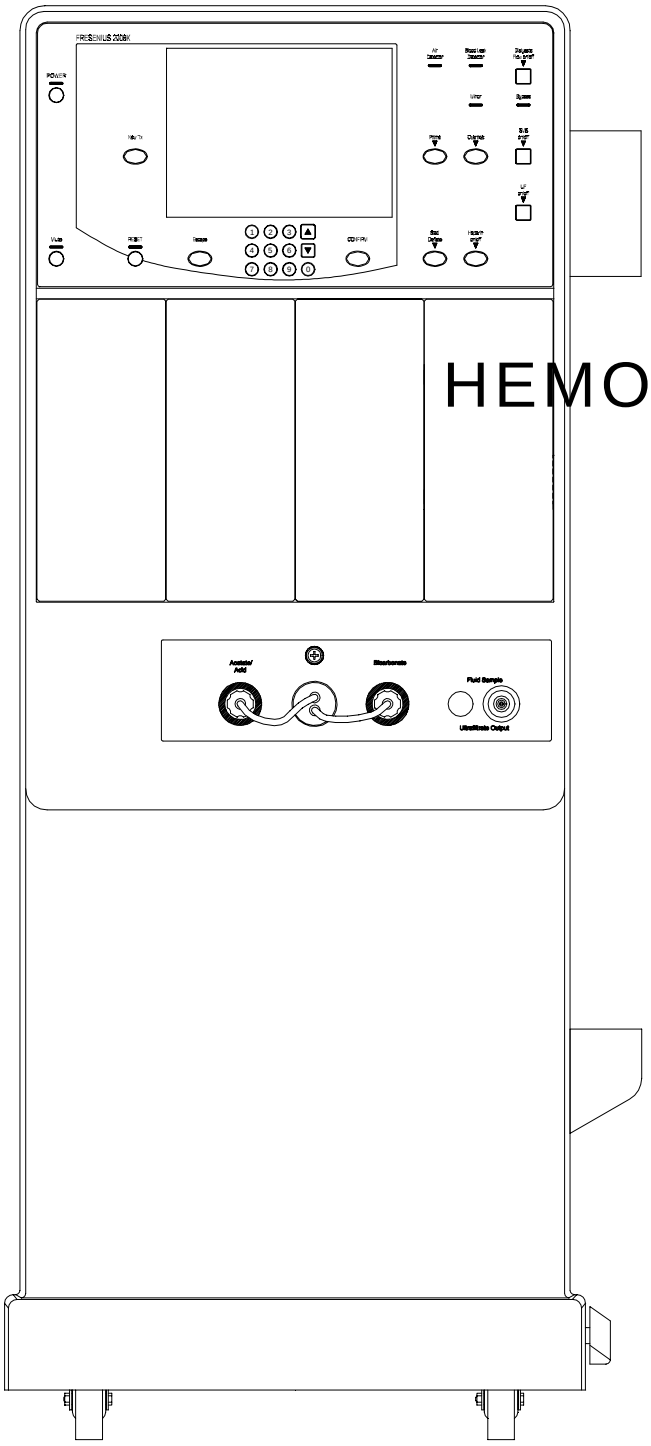
The module is attached to the machine cabinet with two screws and is located under the power supply. The electrical connection to the card cage can be removed once the rear panel has been removed. The blood pressure cuff tubing attaches directly to the module.



Note: Refer to the "Specifications" section for the blood pressure module specifications.

S E C T I O N V I

CALIBRATION & INSTALLATION PROCEDURES



FRESENIUS 2008K HEMODIALYSIS SYSTEM

CALIBRATION PROCEDURES

Part Number 507296 Rev. A

FRESENIUS USA, INC.

2637 Shadelands Drive, Walnut Creek, CA 94598

800-227-2572 or 925-295-0200

REGIONAL EQUIPMENT SPECIALIST: _____

FRESENIUS 2008K
HEMODIALYSIS SYSTEM

CALIBRATION
PROCEDURES

Part Number 507296 Rev. A

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WARNINGS

Shock hazard. Refer servicing to qualified personnel.

Never perform maintenance when a patient is connected to the machine. If possible, remove the machine from the treatment area when it is being serviced. Label the machine to ensure it is not accidentally returned to clinical use before the service work is completed. Always fully test the machine when maintenance is completed. Confirm dialysate conductivity and pH level before returning the machine to clinical use.

The electrical source must be 120 volts, 60 Hz, single phase. The outlet must be a three-conductor type with a hospital-grade receptacle and a ground fault interrupter. Test the polarity and ground integrity before installation and ensure it is maintained thereafter. Failure to do so may result in electrical shock to the operator or patient.

Calibration procedures must be performed using primary standards or by using standards that are regularly calibrated in a program traceable to the National Institute of Standards and Technology (National Bureau of Standards).

Calibrate the Level Detector module for the model of venous line being used. During calibration ensure the filter inside the drip chamber is below the sensor heads. Also verify that the venous clamp fully occludes the line when closed.

Failure to install, operate and maintain this equipment according to the manufacturer's instructions may cause injury or death to the patient or the operator.

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NOTE

This document is written for Fresenius 2008K Hemodialysis Systems using software versions 1.12 or later.

1.0 INTRODUCTION

Calibration involves doing two things. One is making mechanical adjustments, both to the hydraulics and to the electronics. The other part of calibration is storing data in the electronic memory in the machine. The machine uses an EEPROM, which stores calibration data until it is purposely erased and replaced with new data. To store new data in the EEPROM, the machine is operated in Service mode as described in Section 1.2. Service mode also shows important data that is needed to make some of the mechanical adjustments.

Perform the calibration procedures only when needed following repairs, or if the machine fails the performance tests included in the Preventive Maintenance Procedures. Do not re-calibrate the machine routinely to verify normal operation. Instead, use the performance tests included in the Preventive Maintenance procedures to ensure the machine is working properly.

If the machine behaves erratically during calibration, perform the Preventive Maintenance procedures. Clogged filters, leaky O-rings and similar items routinely corrected during Preventive Maintenance are a common cause of intermittent problems. When preparing to re-calibrate the Blood Leak Detector, either perform a bleach rinse first or verify that it has been done recently. The bleach rinse is required to clean the detector tube.

⚠ **Warning!** Once a chemical rinse is performed, the only selection the machine will allow is a mandatory rinse. This information is stored on the functional board. Therefore, if the functional board and EEPROM are swapped out together when troubleshooting a calibration or machine problem, the machine must be rinsed prior to releasing it back into service.

1.1 TEST EQUIPMENT NEEDED

The following supplies and test equipment are required to perform the calibration procedures.

Warning! All of the test equipment used must be maintained and calibrated regularly in accordance with NIST standards. In particular, the conductivity meter must meet the specifications given below. Failure to do so could result in injury or death to the patient or to the operator.

- Fresenius Test Kit (Fresenius part number 150034), which contains two gauges with fittings and hoses for measuring loading pressure and deaeration pressure.
- Fresenius test connectors containing precision resistors that simulate the thermistor resistance at various temperatures (Fresenius part number 190060).
- Dialysate meter to measure dialysate pressure, temperature and conductivity at the ends of the dialysate lines. The meter must be capable of making pressure measurements of from -250 mmHg to +400 mmHg with an accuracy of at least ±2 mmHg up to ±200 mmHg and an accuracy of at least 1% and ±1 mmHg beyond ±200 mmHg. The temperature function of this meter must be accurate within 0.2°C from 20°C to 45°C and must be capable of measuring dialysate temperatures up to 85°C with an accuracy of at least ±4.0°C. The conductivity function of this meter must be accurate to within 0.1 mS over a range of 12 mS to 17 mS at a temperature of 25°C.
- Stopwatch with a resolution to 0.01 second and an accuracy of 0.01% or better.
- Fresenius Buret, 25ml capacity with 0.1ml graduations (Fresenius part number 290104).
- Graduated cylinder: 100ml capacity with a tolerance of 0.60ml at 100ml or better.

- Digital Multimeter to measure dc voltage, ac voltage and resistance with an accuracy of at least 1% + 1 digit for dc voltage measurements 1.5% + 5 digits for ac measurements and 1% + 1 digit for resistance measurements.

- Syringe, 60 cc capacity. Tolerance is not important; the syringe is not used for volume measurements.

For machines equipped with the blood pressure module, the following equipment is also required to test the module as described in this manual:

- Test Device (Fresenius part number 370090). The Test Device contains two air chambers with calibrated volumes.

- Mercury manometer or equivalent pressure meter accurate to within 1 mmHg at pressures up to 335 mmHg.

1.2 OPERATING MODES

The following calibration procedures contain instructions to place the 2008K into Dialysis Mode and Service Mode.

To place the machine in Service Mode, turn the machine power On and wait for the message Press CONFIRM for Service Mode to appear. Once it appears, press the [CONFIRM] key and the message will change to Machine in Service Mode. After the System Initializing process is complete, the machine will be in Service Mode.

If the [CONFIRM] key is not pressed when the Press CONFIRM for Service Mode message is on the screen, the screen will change and the message Machine in Dialysis Mode will appear. After the System Initializing process is complete, the machine will be in Dialysis Mode.

Upon power up in Service Mode, the following screen will appear on the front panel display:

Select a calibration by touching the appropriate calibration button.

Calibration procedures that have a red button must be completed before the machine will operate in Dialysis mode.

Select the desired calibration, then press the [CONFIRM] key to begin the procedure.

⚠ **Caution:** Once a calibration procedure is begun, pressing the [CONFIRM] key usually updates the calibration data in the EEPROM. Be careful not to press the [CONFIRM] key unless you want to change the calibration data. To leave a calibration procedure without changing the data in the EEPROM, press the [Escape] key.

A safety feature in the machine helps prevent mis-calibration. If a calibration value outside of acceptable limits is entered, the machine will reject the calibration data and the message OPERATOR ERROR will appear on the display screen. The data stored in the EEPROM will not be changed if this message appears.

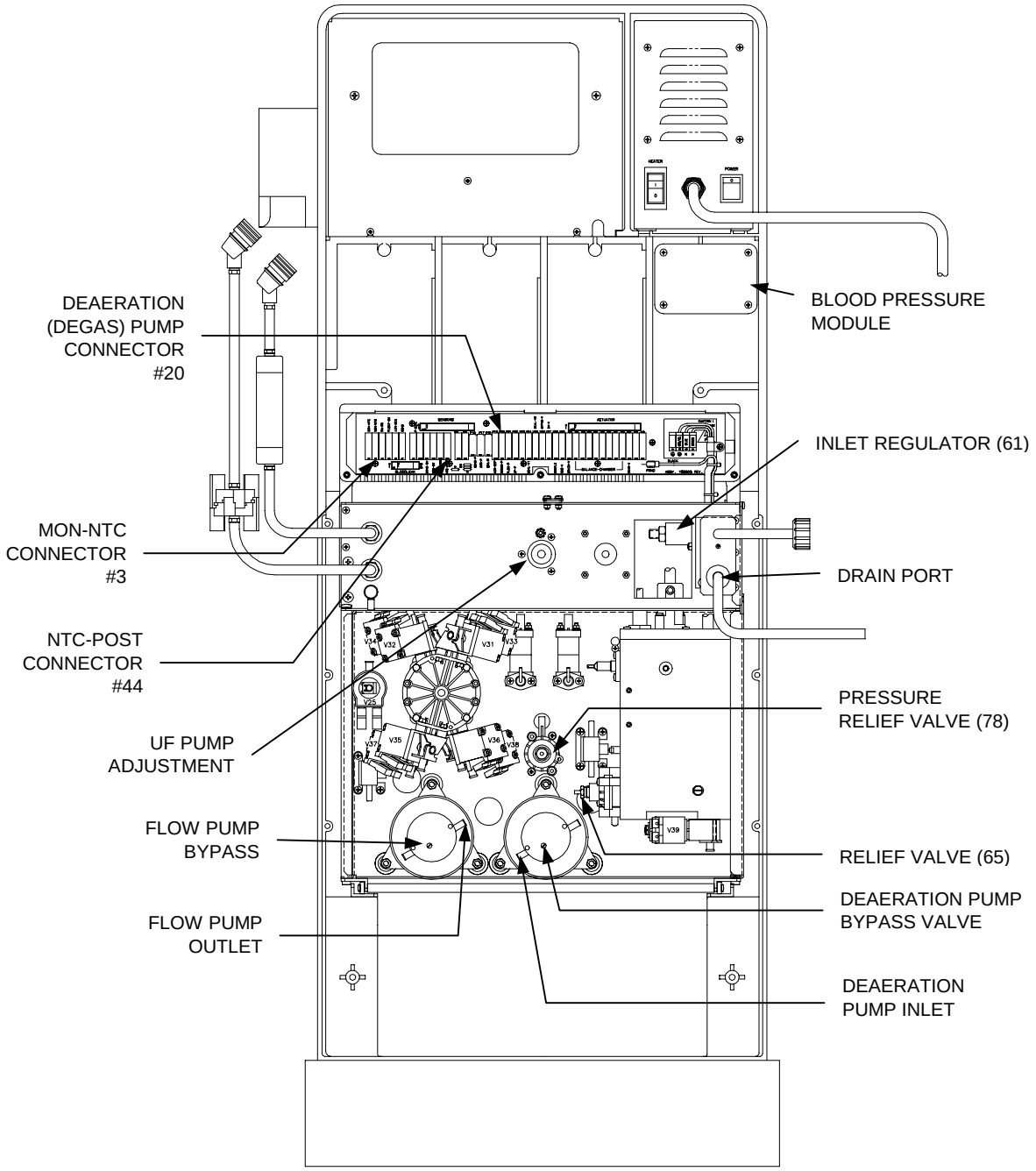


Figure 1. 2008K Rear View.

1.3 FRONT PANEL CONTROLS

The front panel consists of two areas, the touch screen and the control panel. The touch screen is the area under the glass in the center of the front panel. The control panel surrounds the touch screen and it contains the membrane keys. The following illustrates these areas:

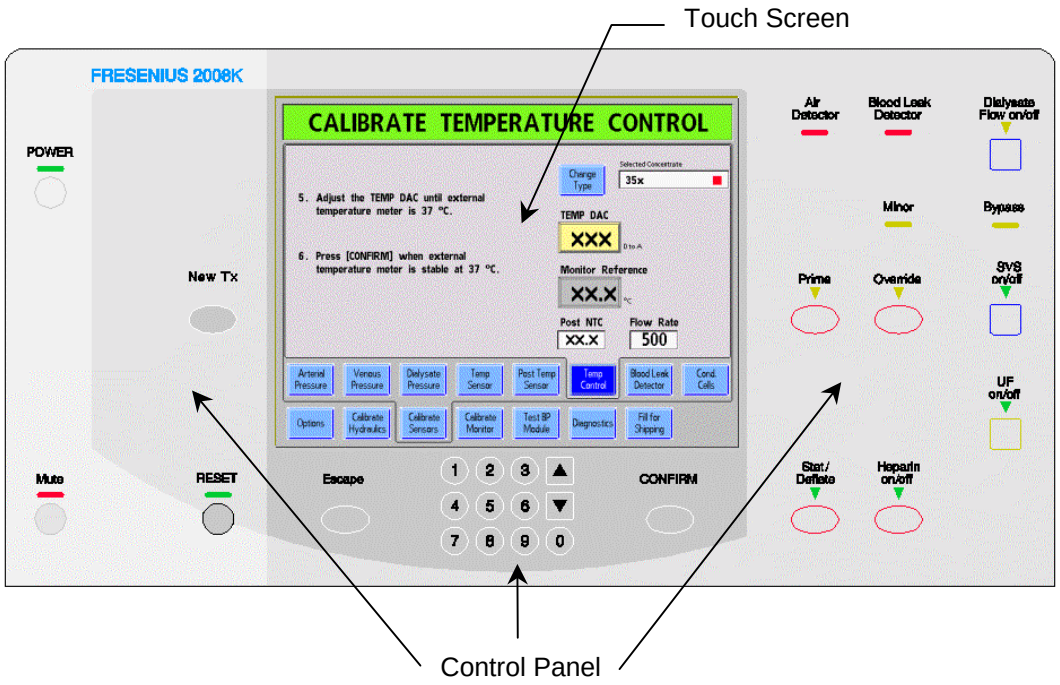


Figure 2. 2008K Front Panel.

Control Panel Operation

Throughout the calibration procedures, whenever a control panel key is to be pressed, the appropriate key name is surrounded by square brackets as in the following example:

> Press the [CONFIRM] key and the screen will change.

In this example, the [CONFIRM] key on the control panel should be pressed.

Touch Screen Operation

The touch screen is designed to display information and is used to enter data. To select a button during a procedure, locate the button on the screen and touch it. Depending on the type of button, the screen will change. Data boxes are also displayed on the touch screen. The following describes the type of buttons and data boxes that will be encountered during the calibration process.

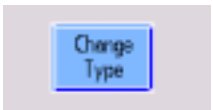
Data Button

A yellow data button is used during calibration to enter a measured volume or value. When the yellow area of the data button is touched, it will change to a darker yellow. The data can be changed using the [▲] or [▼] keys or the value can be entered using the number keys both on the control panel. Once the data is entered, press the [CONFIRM] key and the data button changes back to light yellow. The [Escape] key can be pressed when the data button is dark yellow to abort the data entry and return it to light yellow. The entered data does not get stored until the [CONFIRM] key is pressed.

A gray data button means the button is not active and touching it will have no effect.

Screen Button

Blue rectangles on the touch screen are screen buttons. By touching the blue area of the screen button the display will either change to another screen or the selection of an option will change. A screen button is not active if it is gray.



Data Box

This type of box shows selected data or data the machine is measuring. During the calibration process this type of box is used to verify a value or selection.

1.4 MEASURING FLUID VOLUMES

Several of the following procedures require measuring fluid volumes using graduated cylinders and laboratory burets. When making these measurements do the following:

- Make certain the container is clean and dry before collecting the fluid to be measured. Two drops of fluid are approximately 0.1ml, which is enough to affect the accuracy of critical measurements.

- Ensure that no items such as thermometers or tubing are allowed to come in contact with the fluid in the graduate. Such items will change the calibration of the graduate and affect the accuracy of measurements. Both the total volume indicated and the amount of fluid indicated by each increment on the graduated scale will be incorrect. For example, if a graduate is calibrated in 1ml increments, a piece of tubing in contact with the fluid will cause each increment to be *less* than 1ml, depending upon the total volume of the tubing that penetrates into the fluid.

- Surface tension causes the fluid to curve into a meniscus (see Figure 3). Measure the volume at the bottom of the meniscus curve as shown.

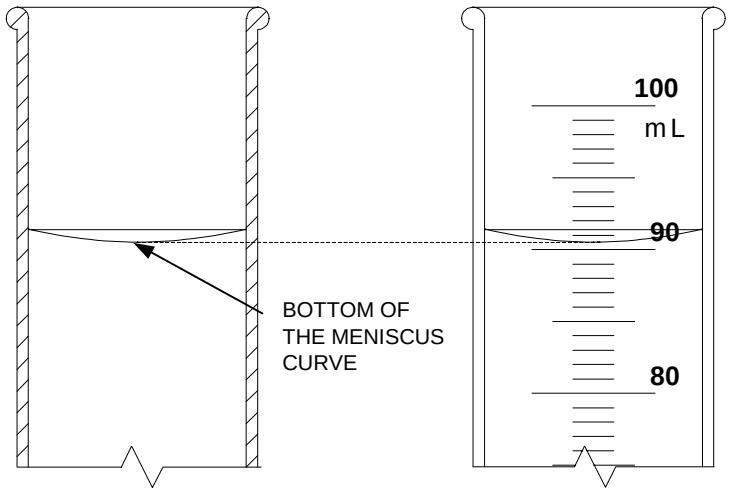


Figure 2. Meniscus Curve.

1.5 CALIBRATE IF REPLACED

During the process of servicing a machine, components may need to be replaced. The following table shows calibrations that must be conducted after replacing certain components.

Replaced Component	Then Calibrate	Refer to:
- Deaeration Pump Head	- Deaeration & Loading Pressure	Sec. 2.2.1
- Deaeration Motor (or rebuild)		
- Loading Pressure Relief Valve		
- Flow Pump Head	- Flow Pressure	Sec. 2.2.2
- Flow Motor (or rebuild)		
- Flow Pressure Relief Valve		
- Balance Chamber	- Balance Chamber Volume	Sec. 2.2.3
- Acid Pump	- Acid Pump Volume	Sec. 2.2.4
- Bicarbonate Pump	- Bicarbonate Pump Volume	Sec. 2.2.5
- UF Pump	- UF Pump Volume	Sec. 2.2.6
- Dialysate Pressure Transducer	- Dialysate Pressure	Sec. 2.3.3
- Temperature Sensor	- Temperature Control	Sec. 2.3.6
- Heater Bar		
- Blood Leak Detector	- Blood Leak	Sec. 2.3.7
- Conductivity Cell	- Conductivity	Sec. 2.3.8
- Functional Board (New EEPROM)	- All Calibrations	All Sections
- Sensor Board	- Arterial Pressure	Sec. 2.3.1
	- Venous Pressure	Sec. 2.3.2
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	- Temperature	Sec. 2.3.6
	- Blood Leak	Sec. 2.3.7
	- Conductivity	Sec. 2.3.8
	- Arterial Pump Rate	Sec. 2.4.3
	- Venous Pump Rate	Sec. 2.4.4
- Blood Pump Module	- Arterial Pressure	Sec. 2.3.1
	- Arterial Pump Rate	Sec. 2.4.3
- Level Detector Module	- Venous Pressure	Sec. 2.3.2
	- Level Detector	Sec. 3.2

Table 1. Calibrate if Replaced.

2.0 SERVICE MODE CALIBRATIONS

Place the machine in Service Mode as described in Section 1.2 to perform the following procedures. The procedures do not have to be completed in any particular order. Go directly to the calibration procedures needed.

If calibration is being performed after working on the hydraulics unit, especially if the inlet water pressure regulator has been changed, we recommend that you calibrate the inlet water pressure regulator as described in Section 3.1 first.

2.1 TOUCH SCREEN CALIBRATION

The touch screen is calibrated from the Service Mode screen.

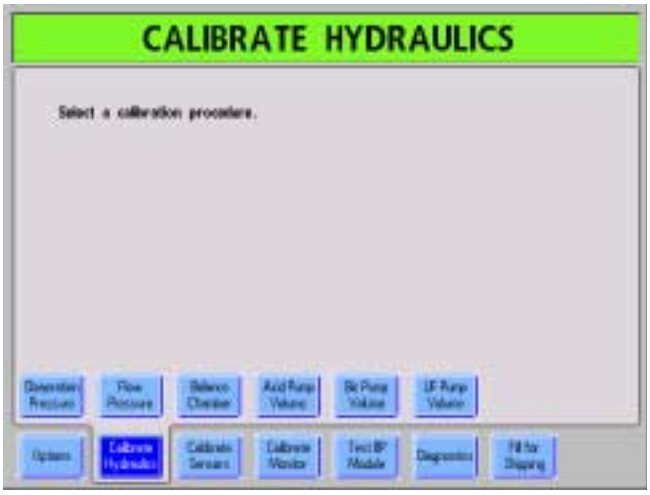
- Press the [New Tx] key to begin the touch screen calibration.

Note: The touch screen needs to be calibrated only when the machine is installed or if the touch screen is replaced.

- Touch the asterisk on the screen. Another asterisk will appear in a different spot on the screen. There are a total of three asterisks that will appear. Touch each asterisk as they appear. When the calibration is complete, the screen will prompt you to power the machine off.

2.2 HYDRAULIC CALIBRATION PROCEDURES

From the Service Mode screen, select the Calibrate Hydraulics screen button. The following screen will appear showing the six hydraulic calibrations:



Perform the following calibrations in the order listed below. To begin a calibration, touch the appropriate calibration screen button.

- Deaeration Pressure
- Flow Pressure
- Balance Chamber
- Acid Pump Volume
- Bicarbonate Pump Volume
- UF Pump Volume

2.2.1 DEAERATION AND LOADING PRESSURE CALIBRATION

From the Calibrate Hydraulics screen, select the Deaeration Pressure screen button. The screen will change to the following:

CALIBRATE DEAERATION PRESSURE
1. Connect a gauge in line at the inlet side of the deaeration pump.
2. Connect a gauge to the red Rinse Port.
3. Press [CONFIRM] to start the Deaeration Pump.
PUMP RATE
XXX

1. Connect a gauge in line at the inlet side of the deaeration pump (See Figure 1, pg. 5).

Note: The inlet side of the deaeration pump is the side with the clear plastic line. The output side has a white reinforced jacket over the line.

---

2. Connect a gauge equipped with a yellow connector into the red ACETATE/ACID port.

3. Press the [CONFIRM] key. The deaeration pump will start and the screen will change.

4. Select the PUMP RATE data button.

   Set the PUMP RATE value to 180, then press the [CONFIRM] key.

5. Adjust the deaeration pump bypass valve (See Figure 1, pg. 5) on the deaeration pump for a reading of -24 inHg on the gauge attached to the deaeration pump. The gauge needle will be wiggling slightly. Set the pressure so the maximum value is -24 inHg and verify that the needle does not go below -25 inHg. If these values cannot be reached, set the deaeration pump bypass valve for the closest reading possible, then select a higher PUMP RATE value until the proper pressure is indicated on the gauge.

6. The loading pressure gauge in the red RINSE port will be cycling between two pressure levels. Adjust pressure relief valve #65 (See Figure 1, pg. 5) for a reading between 18 and 20 psi when the gauge is reading its highest pressure level. Verify that the pressure is greater than 10 psi at the lowest level, and that it is stable within 1 psi at each level.

Note: If a DIASAFE® filter system is installed, adjust pressure relief valve #65 for a reading between 23 and 25 psi when the gauge is reading its highest pressure level.

---

7. Repeat steps 5 and 6 until both readings are correct without further adjustment.

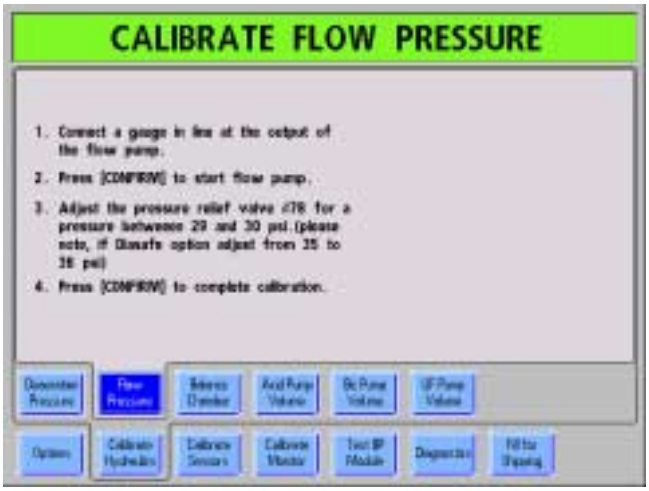
8. Press the [CONFIRM] key to save the data. The screen will change.

   Remove the gauges.

   Press the [CONFIRM] key to complete the calibration and return to the Calibrate Hydraulics screen.

2.2.2 FLOW PRESSURE CALIBRATION

From the Calibrate Hydraulics screen, select the Flow Pressure screen button. The screen will change to the following:


CALIBRATE FLOW PRESSURE
1. Connect a gauge in line at the output of the flow pump.
2. Press [CONFIRM] to start flow pump.
3. Adjust the pressure relief valve #78 for a pressure between 29 and 30 psi.(please note, if Diasafe option adjust from 35 to 36 psi)
4. Press [CONFIRM] to complete calibration.

1. Connect a gauge in line at the output of the flow pump (See Figure 1, pg. 5).

Note: The output side of the flow pump is the side with the white reinforced jacket over the line. The input side has clear plastic line

2. Press the [CONFIRM] key to start the flow pump.

   Locate the flow bypass screw on the back of the flow pump (See Figure 1, pg. 5). Turn the flow bypass screw all the way in (clockwise), then back it out two turns.

3. Adjust pressure relief valve #78 (See Figure 1, pg. 5) for a pressure between 29 and 30 psi indicated on the gauge.

Note: If a DIASAFE® filter system is installed adjust pressure relief valve #78 for a pressure between 35 and 36 psi.

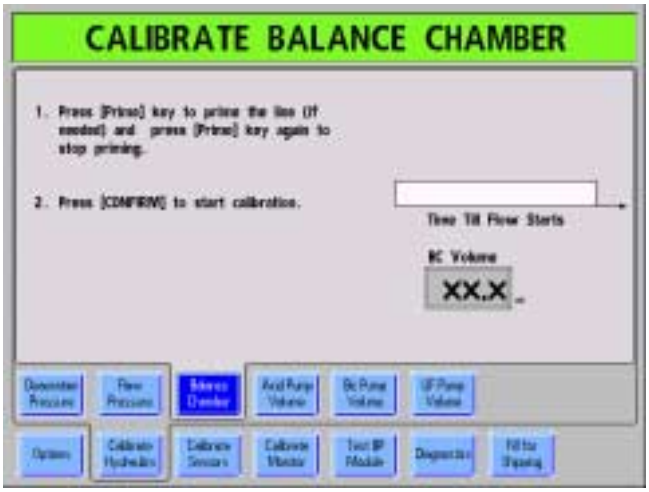
4. Press the [CONFIRM] key to complete the calibration and return to the Calibrate Hydraulics screen.

   Remove the gauge from the flow pump output.

2.2.3 BALANCE CHAMBER VOLUME CALIBRATION

The balance chamber volume is measured at the factory with a high degree of accuracy using equipment usually not available in the field. The chamber volume will not change in use. Record the factory-measured chamber volume for reference should the value need to the replaced in the EEPROM. Only perform the following procedure if the factory-measured volume has been lost, or if the balance chamber has been repaired or replaced.

From the Calibrate Hydraulics screen, select the Balance Chamber screen button. The screen will change to the following:


CALIBRATE BALANCE CHAMBER
1. Press [Prime] key to prime the line (if needed) and press [Prime] key again to stop priming.
2. Press [CONFIRM] to start calibration.
Time Till Flow Starts
BC Volume
XX.X

Note: Be prepared to remove the drain hose from the back of the machine (See Figure 1, pg. 5) and to collect fluid from the drain port with an empty 100ml graduated cylinder.

1. Press the [Prime] key to prime the balance chamber if needed. Press the [Prime] key again to stop this optional priming.

2. Press the [CONFIRM] key to start the calibration. The status box will change indicating the balance chamber is being prepared.

   Once the balance chamber has been prepared, the screen will change and a progress bar will begin to fill from left to right. This bar is showing an approximate 15-second countdown before the contents of the balance chambers are dispensed from the drain port with two pulses of fluid.

3. While this process is going on, remove the drain hose from the back of the machine.

4. Prepare to catch the two pulses of fluid in the empty graduated cylinder by placing it under the drain port.

5. As soon as the progress bar is completely blue, the machine will dispense the two pulses out the drain port.

6. Place the graduated cylinder on a level surface and read the volume of fluid it contains.

   Select the BC Volume data button.

   Set the BC Volume value to the amount collected in the graduated cylinder and then press the [CONFIRM] key.

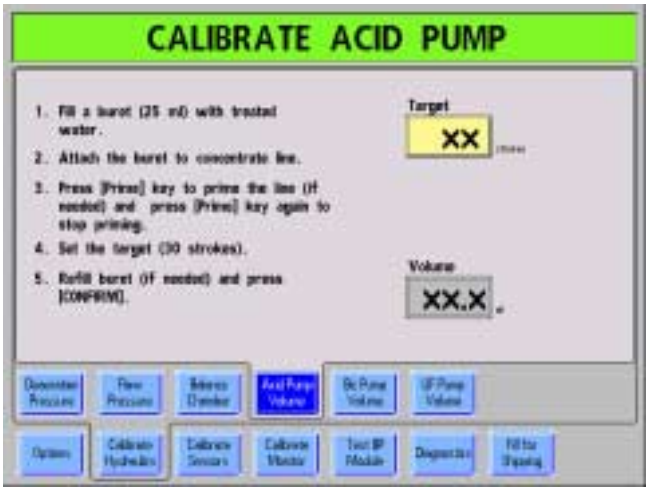
7. Press the [CONFIRM] key again to store the data. The screen will change.

   Replace the drain hose on the drain port.

   Press the [CONFIRM] key to complete the calibration and return to the Calibrate Hydraulics screen.

2.2.4 ACID (CONCENTRATE) PUMP VOLUME CALIBRATION

From the Calibrate Hydraulics screen, select the Acid Pump Volume screen button. The screen will change to the following:


CALIBRATE ACID PUMP
1. Fill a buret (25 ml) with treated water.
2. Attach the buret to concentrate line.
3. Press [Prime] key to prime the line (if needed) and press [Prime] key again to stop priming.
4. Set the target (30 strokes).
5. Refill buret (if needed) and press [CONFIRM].
Target
XX
Volume
XX.X

1. Fill a 25ml buret with treated water or concentrate.

2. Attach the buret to the red concentrate line with a piece of tubing.

3. Press the [Prime] key. The acid pump will begin to stroke. Allow the pump to stroke about 20 times or more to remove the air from the line then press the [Prime] key again to stop the pump.

4. Select the Target data button.

   Set the Target value to 30 strokes, then press the [CONFIRM] key.

5. Refill the buret exactly to the full (0ml) mark.

   Press the [CONFIRM] key. The acid pump will stroke and the screen will change.

6. Wait until the Target value reaches zero.

7. When the Target value reaches zero, the acid pump stops stroking.

Select the Volume data button.

Set the Volume value to the measured volume, then press the [CONFIRM] key.

8. Press the [CONFIRM] key again and the screen will change.

9. Refill the buret exactly to the full (0ml) mark.

Caution: Be sure the buret did not run out of fluid and allow air to be pulled into the machine.

10. If needed, prime the line by pressing the [Prime] key. The acid pump will begin to stroke. Allow the pump to stroke about 20 times or more to remove the air from the line then press the [Prime] key again to stop the pump.

11. Select the Target data button.

    Set the Target value to 30 strokes, then press the [CONFIRM] key.

12. Refill the buret exactly to the full (0ml) mark.

    Press the [CONFIRM] key again. The acid pump will stroke and the screen will change.

13. Wait until the Target value reaches zero.

14. When the Target value reaches zero, the acid pump stops stroking.

    Select the Volume data button.

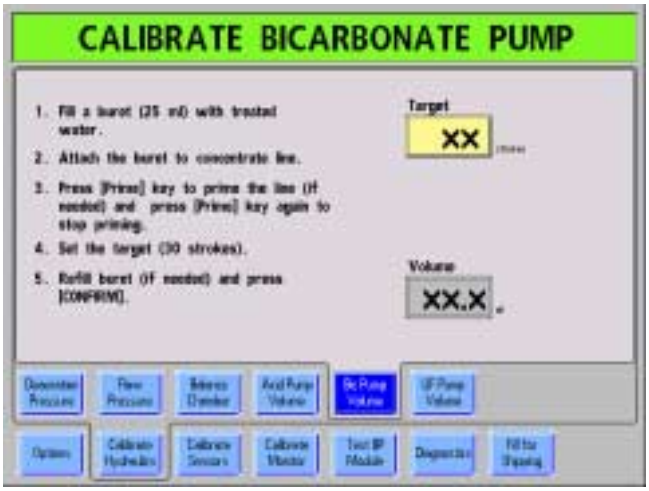
    Set the Volume value to the measured volume, then press the [CONFIRM] key.

15. Press the [CONFIRM] key again to save the data. The screen will change.

    Press the [CONFIRM] key one more time to complete the calibration and return to the Calibrate Hydraulics screen.

2.2.5 BICARBONATE PUMP VOLUME CALIBRATION

From the Calibrate Hydraulics screen, select the Bic Pump Volume screen button. The screen will change to the following:


CALIBRATE BICARBONATE PUMP
1. Fill a buret (25 ml) with treated water.
2. Attach the buret to concentrate line.
3. Press [Prime] key to prime the line (if needed) and press [Prime] key again to stop priming.
4. Set the target (30 strokes).
5. Refill buret (if needed) and press [CONFIRM].
Target
XX
Volume
XX.X

1. Fill a 25ml buret with treated water or concentrate.

2. Attach the buret to the blue bicarbonate line with a piece of tubing.

3. Press the [Prime] key. The bicarbonate pump will begin to stroke.

   Allow the pump to stroke about 20 times or more to remove the air from the line then press the [Prime] key again to stop the pump.

4. Select the Target data button.

   Set the Target value to 30 strokes, then press the [CONFIRM] key.

5. Refill the buret exactly to the full (0ml) mark.

   Press the [CONFIRM] key. The bicarbonate pump will stroke and the screen will change.

6. Wait until the Target value reaches zero.

7. When the Target value reaches zero, the bicarbonate pump stops stroking.

Select the Volume data button.

Set the Volume value to the measured volume, then press the [CONFIRM] key.

8. Press the [CONFIRM] key again and the screen will change.

9. Refill the buret exactly to the full (0ml) mark.

Caution: Be sure the buret did not run out of fluid and allow air to be pulled into the machine.

10. If needed, prime the line by pressing the [Prime] key. The acid pump will begin to stroke. Allow the pump to stroke about 20 times or more to remove the air from the line then press the [Prime] key again to stop the pump.

11. Select the Target data button.

    Set the Target value to 30 strokes, then press the [CONFIRM] key.

12. Refill the buret exactly to the full (0ml) mark.

    Press the [CONFIRM] key again. The bicarbonate pump will stroke and the screen will change.

13. Wait until the Target value reaches zero.

14. When the Target value reaches zero, the bicarbonate pump stops stroking.

    Select the Volume data button.

    Set the Volume value to the measured volume, then press the [CONFIRM] key.

15. Press the [CONFIRM] key again to save the data. The screen will change.

    Press the [CONFIRM] key one more time to complete the calibration and return to the Calibrate Hydraulics screen.

2.2.6 UF PUMP VOLUME CALIBRATION

From the Calibrate Hydraulics screen, select the UF Pump Volume screen button. The screen will change to the following:

1. Remove the dialysate lines from the shunt and place them in a bucket of water.

2. Press the [CONFIRM] key to start the calibration. The screen will change.

3. Remove the tubing from the FLUID SAMPLE / ULTRA-FILTRATE OUTPUT port and connect it to a 25ml buret. Open the buret stopcock.

4. Press the [Prime] key. The UF pump will begin to stroke.

   Allow the pump to stroke about 20 times or more to remove the air from the line then press the [Prime] key again to stop the pump.

   Add or remove fluid from the buret so the meniscus is exactly on the 25ml mark (see Figure 4).

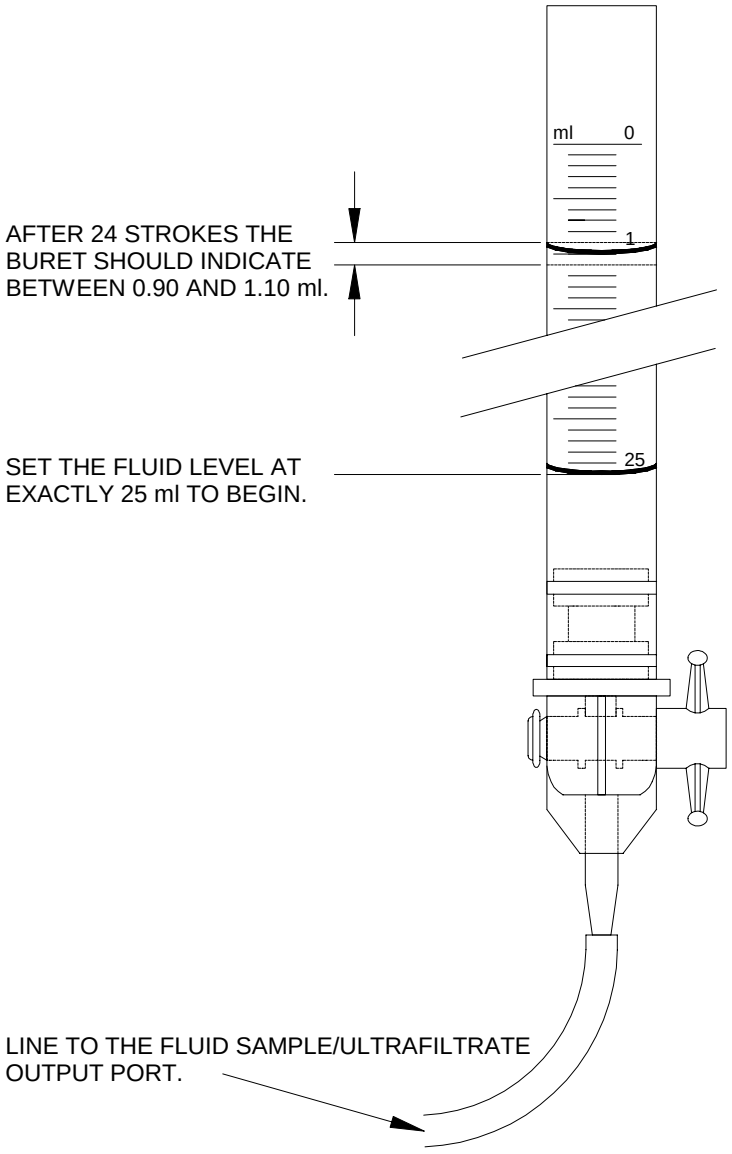


Figure 4. UF Pump Volume Measurement.

5. Select the Target data button.

   Set the Target value to 24 strokes, then press the [CONFIRM] key.

6. Press the [CONFIRM] key again. The UF pump will stroke and the screen will change.

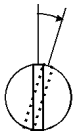
7. Wait until the Target value reaches zero.

8. When the Target value reaches zero, the UF pump will stop. Measure the fluid collected in the buret. The buret scale should indicate between 0.90 and 1.10ml, indicating that between 23.90 and 24.10ml of fluid was collected (see Figure 4). If the volume collected is not within this range, adjust the UF pump volume as follows:

    - On the rear center of the hydraulics assembly, remove the plastic cap covering the pump adjustment screw (See Figure 1, pg. 5).

    - Loosen the locking nut and turn the screw clockwise to decrease or counter-clockwise to increase the pump volume.

    Note: Turning the adjustment screw approximately the width of the screwdriver slot will change the amount of fluid collected in 24 strokes by about 0.25ml. After making adjustments, prime the pump again.



    - Tighten the locking nut before proceeding.

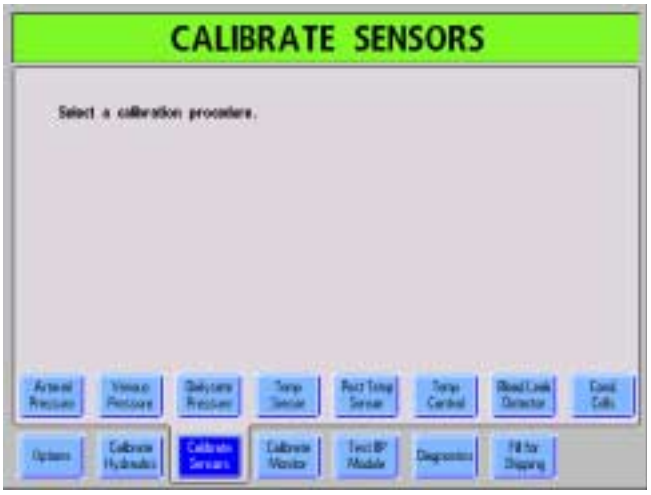
    - Press the [Escape] key and repeat the UF Pump Volume calibration until the fluid fills the buret to between 0.90 and 1.10 on the scale after 24 strokes of the UF pump.

9. Replace the plastic cap on the UF pump adjustment.

    Press the [CONFIRM] key to complete the calibration and return to the Calibrate Hydraulics screen.

2.3 SENSOR CALIBRATION PROCEDURES

From the Service Mode screen, select the Calibrate Sensors screen button. The following screen will appear showing the eight sensor calibrations:



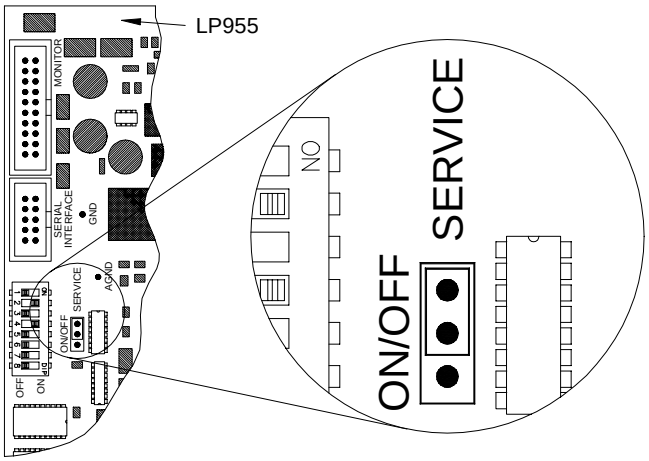
Perform the following calibrations in the order listed below. To begin a calibration, touch the appropriate calibration screen button.

- Arterial Pressure
- Venous Pressure
- Dialysate Pressure
- Temperature Sensor
- Post Temperature Sensor
- Temperature Control
- Blood Leak Detector
- Conductivity Cells

2.3.1 ARTERIAL PRESSURE CALIBRATION

The K arterial blood pump does not use potentiometers to calibrate the arterial pressure. Instead, it stores a value in the blood pump. In order to calibrate the arterial pressure, the pump must be put into its own service mode. This is done by moving the Service Jumper located on the blood pump LP955 board. Refer to Figure 5 for location and positioning of the Service Jumper.

Note: The DIP switches and Service Jumper on the blood pump must be set prior to turning the machine ON.



Dip switch	Description
1	ON for future use
	OFF for use on the 2008K
2	ON for Pre-Pump Arterial Pressure
	OFF for Post-Pump Arterial Pressure
3	Not Used
4	ON for blood pump stop alarm after 30 sec
	OFF for blood pump stop alarm after 15 sec
5	Not Used
6	Not Used
7	Not Used
8	ON for tubing diameter selection 2 to 10mm (0.2mm increments)
	OFF for tubing diameter selection 2.6, 4.8, 6.4 and 8.0mm only

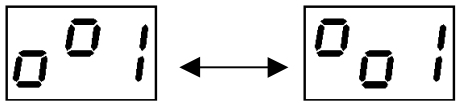
In Service Mode

Not In Service Mode

Figure 5. K Blood Pump DIP switches & Service Jumper.

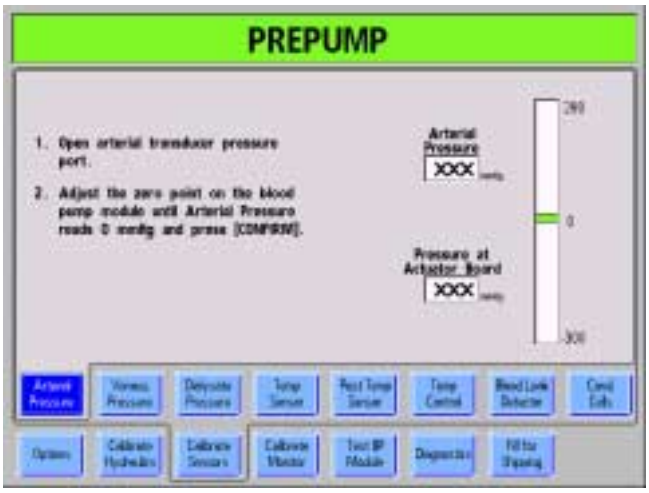
The following procedure calibrates the pressure sensor on the K arterial blood pump.

- With the machine turned OFF, position the blood pump Service Jumper into the In Service Mode position.
- Locate DIP switch 2 on the blood pump LP955 board and configure it as follows:
    - For prepump, DIP switch 2 must be in the ON position
    - For postpump, DIP switch 2 must be in the OFF position
- With the 2008K machine in Service mode, turn the power ON.
- When the power up sequence is complete, the blood pump display will be alternating between these two displays:



Note: If the above display has a number 2 instead of a number 1, press the [▼] down key on the blood pump control panel to change it to 1.

From the Calibrate Sensors screen, select the Arterial Pressure screen button. The screen will change to the following:

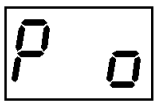

PREPUMP
1. Open arterial transducer pressure port.
2. Adjust the zero point on the blood pump module until Arterial Pressure reads 0 mmHg and press [CONFIRM].
Arterial Pressure
XXX
Pressure at Actuator Board
XXX

Note: Depending on the HARDWARE OPTION set for the ART PUMP option, the above display may read POSTPUMP instead of PREPUMP. The bargraph scale will also be different (500 to –80mmHg).

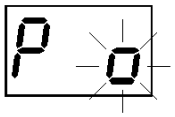
1. Open arterial transducer port $\mathbf{P}_{ART.}$ on the blood pump module to air (atmospheric pressure).

Note: Use the Arterial Level Adjust [▲] key on the blood pump control panel to abort the calibration process without changing the stored DAC value on the blood pump.

Press the [Start/Stop] key on the blood pump and its display will change to the following:



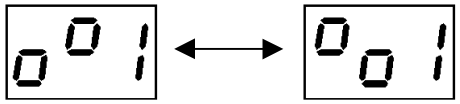
Press the [Start/Stop] key again and the small zero will start to flash.



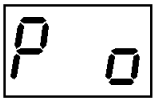
2. Use the [▲] and [▼] keys on the blood pump to adjust the Arterial Pressure data box on the 2008K display to indicate 0 mmHg.

   Press the [CONFIRM] key and the 2008K display will change.

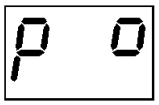
   Press the [Start/Stop] key on the blood pump and its display will change back to the following alternating display:



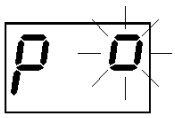
   Press the [Start/Stop] key again and the display will change to the following:



   Press the [▲] key on the blood pump to change it to the following:



   Press the [Start/Stop] key and the small zero will start to flash.

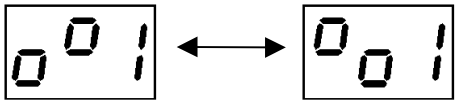


3. Attach a syringe and a calibrated pressure gauge to the **P**$_{ART.}$ port using a T- fitting.

4. Push the syringe plunger in to show a pressure of 200mmHg on the external pressure gauge.

5. While holding this pressure, do the following:

   - Use the [▲] and [▼] keys on the blood pump to adjust the Arterial Pressure data box on the 2008K display to indicate 200mmHg.
   - Press the [CONFIRM] key and the 2008K display will change.
   - Press the [Start/Stop] key on the blood pump and its display will change back to the alternating display:



   - Verify that the Arterial Pressure and Pressure at Actuator Board meter boxes are within 10 mmHg of each other.

Note: After pressing the [CONFIRM] key, a delay of approximately 8 seconds may occur before the Pressure at Actuator Board data box changes to be within 10 mmHg of the Arterial Pressure data box on the display screen.

6. Pressurize the $\mathbf{P}_{ART.}$ port by either pushing or pulling on the syringe.

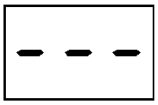
7. Verify that the Arterial Pressure and Pressure at Actuator Board meter boxes can reach at least 290mmHg (510mmHg for postpump) and that they are within 10mmHg of each other.

   Verify that the Arterial Pressure and Pressure at Actuator Board meter boxes can reach at least -310mmHg (-90mmHg for postpump) and that they are within 10mmHg of each other.

8. Press the [CONFIRM] key to save the data. The screen will change.

Caution: The following step must be performed on the blood pump or the calibration data you just collected and tested will be lost when the machine is turned off.

Press the [▲] and [▼] keys on the blood pump at the same time to save the DAC values to the blood pump memory. While pressing both keys, the blood pump display will show dashes as shown below:

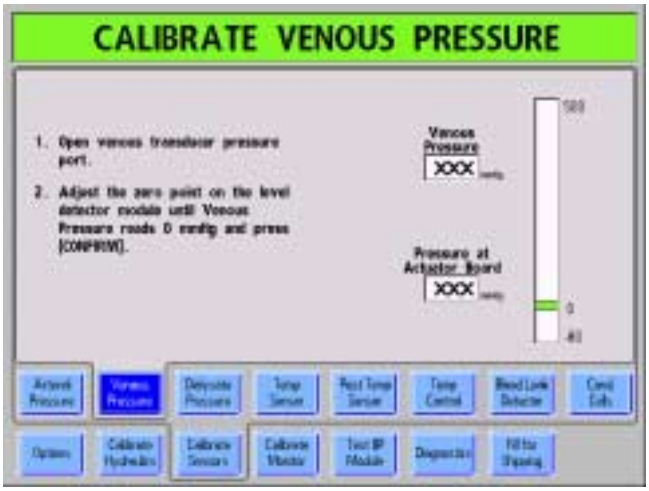


Press the [CONFIRM] key to complete the calibration and return to the Calibrate Sensors screen.

Power the machine OFF and move the blood pump Service Jumper into the Not in Service Mode position (see Figure 5).

2.3.2 VENOUS PRESSURE CALIBRATION

From the Calibrate Sensors screen, select the Venous Pressure screen button. The screen will change to the following:


CALIBRATE VENOUS PRESSURE
1. Open venous transducer pressure port.
2. Adjust the zero point on the level detector module until Venous Pressure reads 0 mmHg and press [CONFIRM].
Venous Pressure
XXX
Pressure at Actuator Board
XXX

1. Open the venous transducer port **P**$_{VEN.}$ on the level detector module to air (atmospheric pressure).

2. Adjust the ZERO SET potentiometer (see Figure 6) so that the Venous Pressure data box indicates zero mmHg.

   Press the [CONFIRM] key and the screen will change.

3. Attach a syringe and a calibrated pressure gauge to the **P**$_{VEN.}$ port using a **T**- fitting.

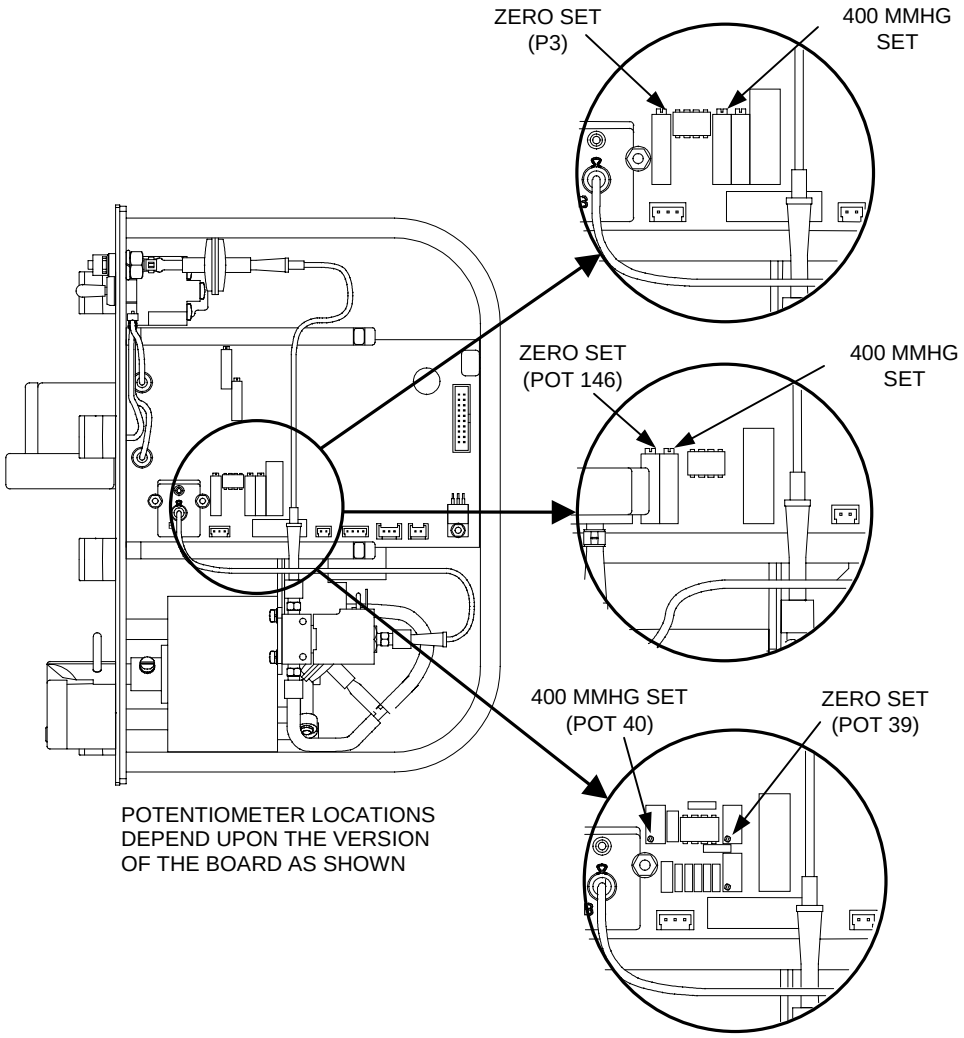


Figure 6. Venous Pressure Display Adjustments.

4. Push the syringe plunger in to show a pressure of 400mmHg on the external pressure gauge.

5. While holding this pressure, do the following:

- Adjust the 400 MMHG SET potentiometer (see Figure 6) so the Venous Pressure data box indicates 400 mmHg.
- Press the [CONFIRM] key and the screen will change.
- Verify that the Venous Pressure and Pressure at Actuator Board meter boxes are within 10 mmHg of each other.

Note: After pressing the [CONFIRM] key, a delay of approximately 8 seconds may occur before the Pressure at Actuator Board data box changes to be within 10 mmHg of the Venous Pressure data box on the display screen.

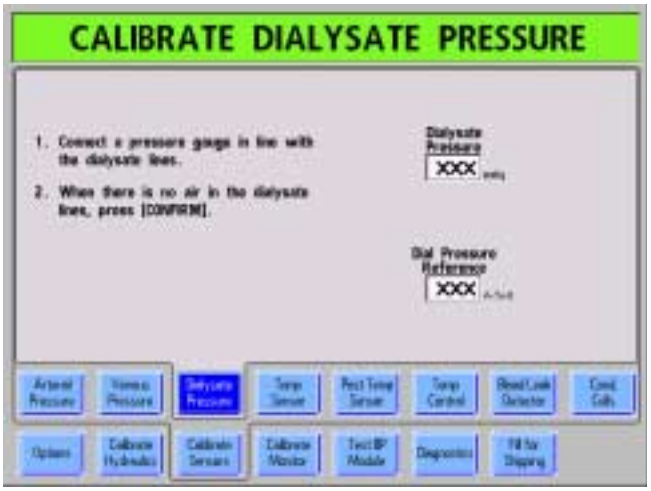
6. Pressurize the $\mathbf{P}_{VEN.}$ port by either pushing or pulling on the syringe.
7. Verify that the Venous Pressure and Pressure at Actuator Board meter boxes can reach at least 510mmHg and that they are within 10mmHg of each other.

   Verify that the Venous Pressure and Pressure at Actuator Board meter boxes can reach at least –90mmHg and that they are within 10mmHg of each other.
8. Press the [CONFIRM] key to save the calibration. The screen will change.

   Press the [CONFIRM] key again to complete the calibration and return to the Calibrate Sensors screen.

2.3.3 DIALYSATE PRESSURE CALIBRATION

From the Calibrate Sensors screen, select the Dialysate Pressure screen button. The screen will change to the following:


CALIBRATE DIALYSATE PRESSURE
1. Connect a pressure gauge in line with the dialysate lines.
2. When there is no air in the dialysate lines, press [CONFIRM].
Dialysate Pressure
XXX
Dial Pressure Reference
XXX

1. Hang a four-way connector on the I.V. pole at the normal dialyzer height. Remove the dialyzer lines from the shunt and attach them to the connector.

Note: The four-way connector is included in the Fresenius Test Kit part number 150034.

Connect a 30cc syringe to one of the four-way connector outlets and clamp the tubing.

Connect an external pressure gauge to the remaining four-way connector outlet and clamp the tubing.

2. Dialysate should be flowing, as indicated by the flow indicator in the dialysate lines.

Note: If there is no dialysate flow through the flow indicator, make sure the yellow [Dialysate Flow on/off] light is off and the shunt door is closed.

Wait until no air is visible passing through the flow indicator, then press the [CONFIRM] key. The screen will change.

3. Press the [Dialysate Flow on/off] key to stop dialysate flow.

Unclamp the lines leading to the 30cc syringe and the pressure gauge.

4. Use the syringe to create a pressure reading of 0mmHg on the external pressure gauge.

5. While holding this pressure, press the [CONFIRM] key. The screen will change.

6. Use the syringe to create pressure reading of -250mmHg on the external pressure gauge.

7. While holding this pressure, press the [CONFIRM] key to save the data. The screen will change.

8. Press the [Dialysate Flow on/off] key to start dialysate flow.

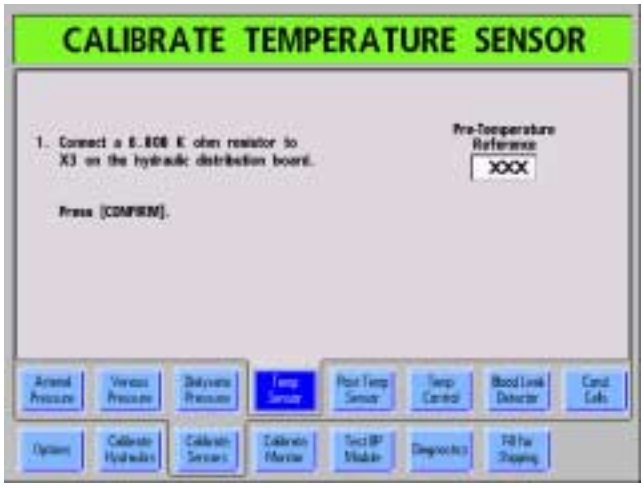
9. Open the shunt and remove the lines from the external pressure gauge. Replace them on the shunt and close the door.

   Press the [CONFIRM] key to complete the calibration and return to the Calibrate Sensors screen.

2.3.4 TEMPERATURE SENSOR CALIBRATION

Perform the temperature sensor calibration as follows using the test connector set referenced in Section 1.1. The display screen calls for connecting specific resistances to the X3 (MON-NTC) connector position on the distribution panel (See Figure 1, pg. 5) for each test. The test connectors contain resistors which are the closest 1% tolerance resistor available to these values. In the following procedure, each test connector is identified by the number marked on its cover.

From the Calibrate Sensors screen, select the Temp Sensor screen button. The screen will change to the following:



1. Remove the distribution board cover from the back of the machine.

   Unplug the X3 (MON-NTC) connector from the distribution board.

   Connect test connector 34 (6.808KΩ) into X3 (MON-NTC) connection on the distribution board.

   Press the [CONFIRM] key to save the data. The screen will change.

2. Remove the previous test connector and connect test connector 40 (5.117KΩ) into X3 (MON-NTC) connection on the distribution board.

   Press the [CONFIRM] key to save the data. The screen will change.

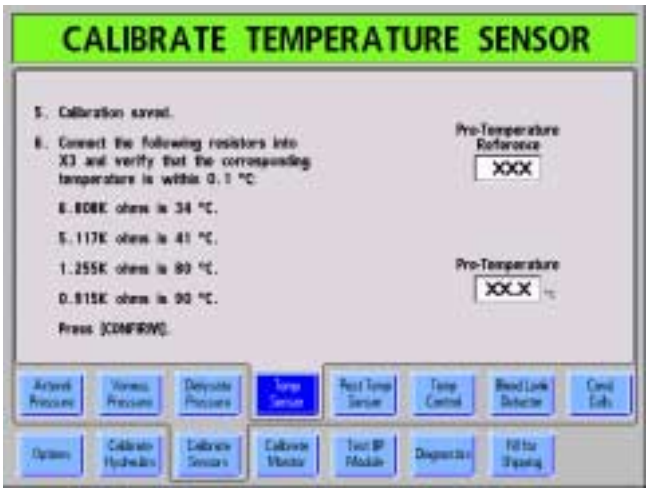
3. Remove the previous test connector and connect test connector 80 (1.255KΩ) into X3 (MON-NTC) connection on the distribution board.

   Press the [CONFIRM] key to save the data. The screen will change.

4. Remove the previous test connector and connect test connector 90 (0.915KΩ) into X3 (MON-NTC) connection on the distribution board.

   Press the [CONFIRM] key to save the data.

5. The screen will confirm the calibration has been saved:


CALIBRATE TEMPERATURE SENSOR
5. Calibration saved.
6. Connect the following resistors into X3 and verify that the corresponding temperature is within 0.1 °C:
8.808K ohms is 34 °C.
5.117K ohms is 41 °C.
1.255K ohms is 80 °C.
0.915K ohms is 90 °C.
Press [CONFIRM].
Pre-Temperature Reference
XXX
Pre-Temperature
XX.X

6. Insert each of the test connectors into X3 (MON-NTC) to confirm the saved calibration data. Each connector must be within 0.1°C of the Pre-Temperature data box.

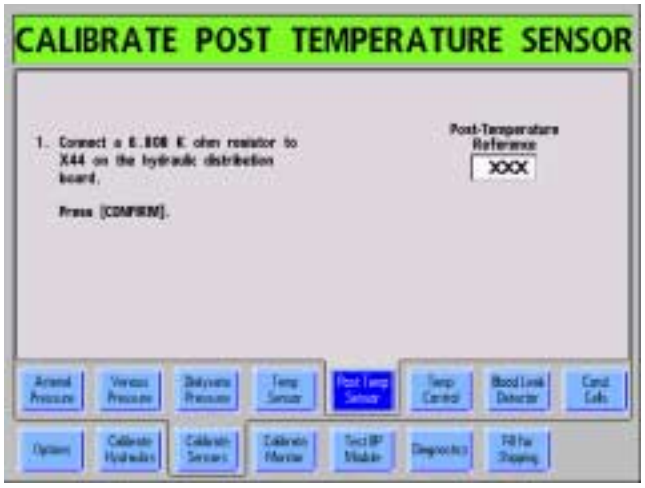
   Press the [CONFIRM] key to complete the calibration and return to the Calibrate Sensors screen.

   Remove the test connector and replace the X3 (MON-NTC) connector on the distribution board.

2.3.5 POST TEMPERATURE SENSOR CALIBRATION

Perform the post temperature sensor calibration as follows using the test connector set referenced in Section 1.1. The display screen calls for connecting specific resistances to the X44 (NTC-POST) connector position on the distribution panel (See Figure 1, pg. 5) for each test. The test connectors contain resistors which are the closest 1% tolerance resistor available to these values. In the following procedure, each test connector is identified by the number marked on its cover.

From the Calibrate Sensors screen, select the Post Temp Sensor screen button. The screen will change to the following:



1. Remove the distribution board cover from the back of the machine.

   Unplug the X44 (NTC-POST) connector from the distribution board.

   Connect test connector 34 (6.808KΩ) into X44 (NTC-POST) connection on the distribution board.

   Wait for the Post-Temperature Reference data box to stabilize.

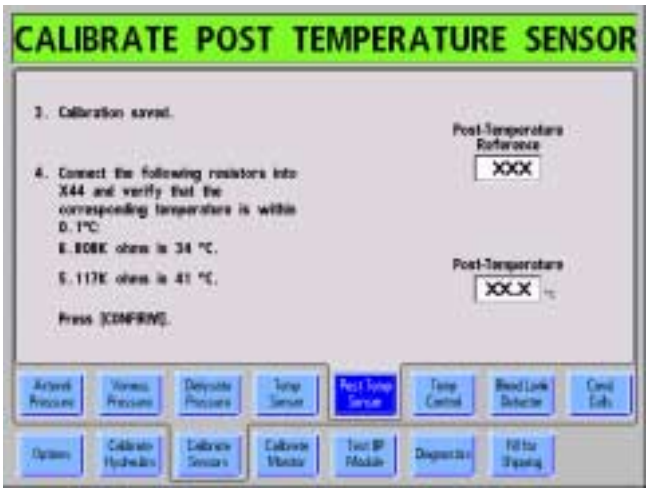
   Press the [CONFIRM] key to save the data. The screen will change.

2. Remove the previous test connector and connect test connector 40 (5.117KΩ) into X44 (NTC-POST) connection on the distribution board.

   Wait for the Post-Temperature Reference data box to stabilize.

   Press the [CONFIRM] key to save the data.

3. The screen will confirm the calibration has been saved:


CALIBRATE POST TEMPERATURE SENSOR
3. Calibration saved.
4. Connect the following resistors into X44 and verify that the corresponding temperature is within 0.1°C:
8.808K ohms is 34 °C.
5.117K ohms is 41 °C.
Press [CONFIRM].
Post-Temperature Reference
XXX
Post-Temperature
XX.X

4. Insert each of the test connectors into X44 (NTC-POST) to confirm the saved calibration data. Each connector must be within 0.1°C of the Post-Temperature data box.

   Press the [CONFIRM] key to complete the calibration and return to the Calibrate Sensors screen.

   Remove the test connector and replace the X44 (NTC-POST) connector on the distribution board.

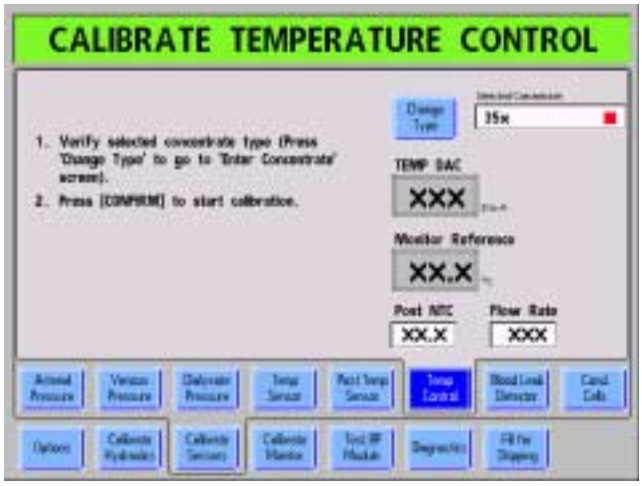
2.3.6 TEMPERATURE CONTROL CALIBRATION

If the machine is not equipped with the CRRT option and the slow flow option is disabled, perform Section 2.3.6.1. If the machine is equipped with the CRRT option or the slow flow option is enabled, perform Section 2.3.6.2.

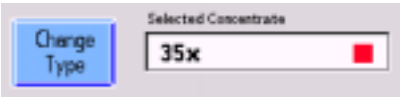
2.3.6.1 TEMPERATURE CONTROL CALIBRATION (SLOW FLOW NOT ENABLED)

Replace any panels that have been removed so that the machine is closed up as it would be in normal operation. It is important for this calibration that ventilation around the hydraulics unit be the same as it is when the machine is used for dialysis.

From the Calibrate Sensors screen, select the Temp Control screen button. The screen will change to the following:



1. Verify in the Selected Concentrate box that the type of concentrated used is selected.



If not correct, press the Change Type button.

Note: If the Change Type button is pressed, the Enter Conc screen will be displayed. Change the selected concentrate and then select Calibrate Sensors screen button and then Temp Control screen button to return to step 1 above.

2. Press the [CONFIRM] key to start the calibration. The screen will change.
3. Connect the red and blue concentrate connectors to concentrate solutions as in normal dialysis operation.
4. Remove the dialysate lines from the shunt and connect them to an external temperature meter. Close the shunt door.
5. Press the [CONFIRM] key and the screen will change.
6. Select the TEMP DAC data button.

   Adjust the TEMP DAC value, then press the [CONFIRM] key.

Note: Changing the DAC value by 2 or 3 units will produce a temperature change of about 0.1°C. Wait for the temperature to change and stabilize before changing it again to avoid overshooting the proper setting.

Note: The TEMP DAC value does not take effect until the [CONFIRM] key is pressed and the TEMP DAC data button is light yellow.

The temperature of the dialysate shown on the external meter will change after a delay. Find a TEMP DAC value that produces a temperature on the external meter of 37°C.

Wait five minutes after the last adjustment of the TEMP DAC value, then verify that the temperature on the external meter has remained at 37°C. If not, change the TEMP DAC value, and wait five minutes again.

7. When the temperature remains at 37°C, press the [CONFIRM] key. The screen will change.

8. Select the Monitor Reference data button.

   Adjust the value shown for Monitor Reference until it matches the external temperature meter at 37°C and then press the [CONFIRM] key.

9. Press the [CONFIRM] key again to save the data. The screen will change.

   Open the shunt to stop the dialysate flow, remove the lines from the external meter and replace them on the shunt.

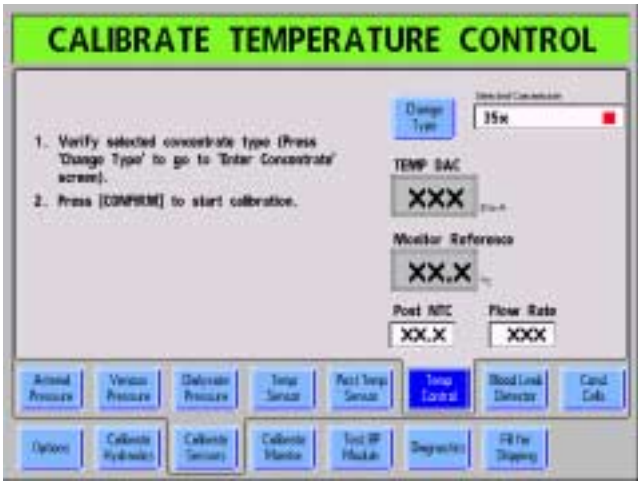
   Press the [CONFIRM] key to complete the calibration and return to the Calibrate Sensors screen.

2.3.6.2 TEMPERATURE CONTROL CALIBRATION (SLOW FLOW OR CRRT)

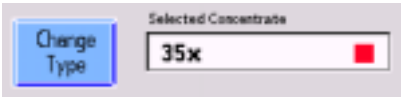
If the CRRT option is installed or if the slow flow option is enabled, the Temp Control calibration is done in two parts. The DAC and temperature monitor calibration is performed at 500ml/min flow rate and then it is calibrated at a 100ml/min flow rate.

Replace any panels that have been removed so that the machine is closed up as it would be in normal operation. It is important for this calibration that ventilation around the hydraulics unit be the same as it is when the machine is used for dialysis.

From the Calibrate Sensors screen, select the Temp Control screen button. The screen will change to the following:



1. Verify in the Selected Concentrate box that the type of concentrated used is selected.



If not correct, press the Change Type button.

Note: If the Change Type button is pressed, the Enter Conc screen will be displayed. Change the selected concentrate and then select Calibrate Sensors screen button and then Temp Control screen button to return to step 1 above.

2. Press the [CONFIRM] key to start the calibration. The screen will change.
3. Connect the red and blue concentrate connectors to concentrate solutions as in normal dialysis operation.
4. Remove the dialysate lines from the shunt and connect them to an external temperature meter. Close the shunt door.
5. Press the [CONFIRM] key and the screen will change.
6. The Temp Control calibration begins with the flow at 500ml/min.

   Select the TEMP DAC data button.

   Adjust the TEMP DAC value, then press the [CONFIRM] key.

Note: Changing the DAC value by 2 or 3 units will produce a temperature change of about 0.1°C. Wait for the temperature to change and stabilize before changing it again to avoid overshooting the proper setting.

Note: The TEMP DAC value does not take effect until the [CONFIRM] key is pressed and the TEMP DAC data button is light yellow.

The temperature of the dialysate shown on the external meter will change after a delay. Find a TEMP DAC value that produces a temperature on the external meter of 37°C.

Wait five minutes after the last adjustment of the TEMP DAC value, then verify that the temperature on the external meter has remained at 37°C. If not, change the TEMP DAC value, and wait five minutes again.

7. When the temperature remains at 37°C, press the [CONFIRM] key. The screen will change.

8. Select the Monitor Reference data button.

   Adjust the value shown for Monitor Reference until it matches the external temperature meter at 37°C and then press the [CONFIRM] key.

9. Press the [CONFIRM] key again and the screen will change.

10. The Temp Control calibration now changes the flow to 100ml/min.

    Select the TEMP DAC data button.

    Adjust the TEMP DAC value, then press the [CONFIRM] key.

Note: The TEMP DAC value does not take effect until the [CONFIRM] key is pressed and the TEMP DAC data button is light yellow.

The temperature of the dialysate shown on the external meter will change after a delay. Find a TEMP DAC value that produces a temperature on the external meter of 37°C. Be patient, the 100ml/min flow rate calibration takes time.

Note: Depending on the incoming water temperature, the DAC value during the 100ml/min flow calibration may have to be set to the maximum (255). If the temperature is less than 37°C, the DAC value is at 255, and enough time has passed, go ahead and save the DAC value of 255. This circumstance will be compensated for in dialysis or CRRT modes.

Wait five minutes after the last adjustment of the TEMP DAC value, then verify that the temperature on the external meter has remained at 37°C. If not, change the TEMP DAC value, and wait five minutes again.

11. When the temperature remains at 37°C, press the [CONFIRM] key. The screen will change.

12. Select the Monitor Reference data button.

    Adjust the value shown for Monitor Reference until it matches the external temperature meter at 37°C and then press the [CONFIRM] key.

13. Press the [CONFIRM] key again to save the data. The screen will change.

    Open the shunt to stop the dialysate flow, remove the lines from the external meter and replace them on the shunt.

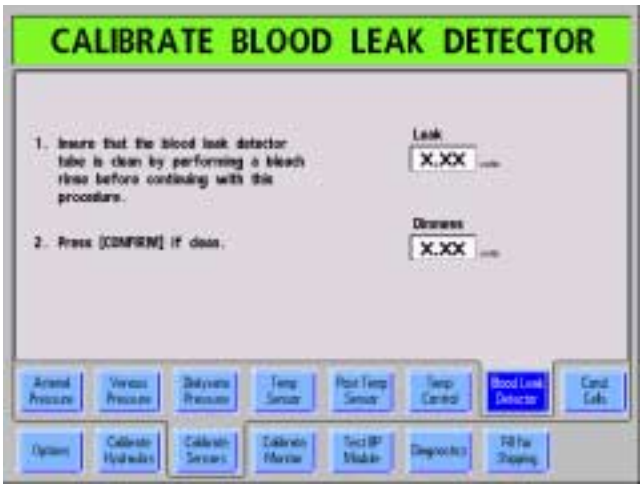
    Press the [CONFIRM] key to complete the calibration and return to the Calibrate Sensors screen.

2.3.7 BLOOD LEAK CALIBRATION

The glass tube in the blood leak detector must be clean before the blood leak detector calibration can be completed successfully. The glass tube in the detector is cleaned by performing a bleach rinse, which washes the tube out along with the rest of the hydraulics.

There are two calibrations performed on the Blood Leak Detector. One calibrates the detector itself and the other calibrates the dimness circuits. Perform the procedures as described below.

From the Calibrate Sensors screen, select the Blood Leak Detector screen button. The screen will change to the following:


CALIBRATE BLOOD LEAK DETECTOR
1. Insure that the blood leak detector tube is clean by performing a bleach rinse before continuing with this procedure.
2. Press [CONFIRM] if done.
Leak
X.XX
Dimness
X.XX

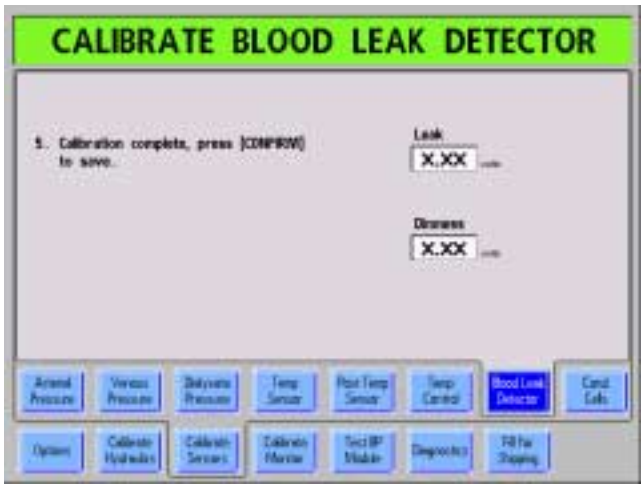
Note: The blood leak and blood dimness calibration is performed automatically. Once started, the calibration will proceed on its own until the calibration complete screen is displayed.

1. Verify that the machine has received a bleach rinse recently, or perform a bleach rinse as described in the Operator's Manual before calibrating the blood leak detector.

2. Press the [CONFIRM] key. The screen will change and the blood leak calibration will start.

3. The first calibration that is performed is the automatic blood leak calibration. When its finished, the screen will change.

4. The second calibration that is performed is the automatic blood dimness calibration. When its finished, the following calibration complete screen will be displayed:



5. Press the [CONFIRM] key to save the data. The screen will change.

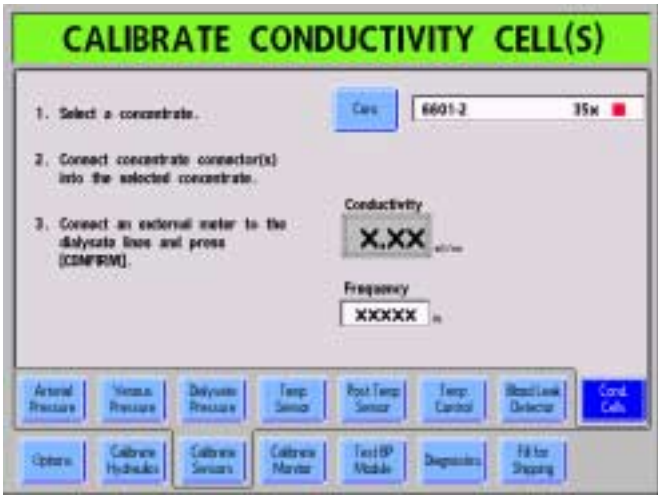
   Press the [CONFIRM] key again to complete the calibration and return to the Calibrate Sensors screen.

2.3.8 CONDUCTIVITY CELLS CALIBRATION

Machines equipped with Online Clearance (OLC) have two conductivity cells. The first conductivity cell is PRE dialyzer and the second conductivity cell is POST dialyzer.

Note: If the Clearance option is set to NO in Hardware Options, the post conductivity cell will not be calibrated.

From the Calibrate Sensors screen, select the Cond Cells screen button. The screen will change to the following:



1. Identify the concentrate you will be using to calibrate the conductivity cells.

   Select the concentrate by pressing the Conc button. The screen will change showing a list of concentrates. Use the [▲] or [▼] keys to scroll through the list to locate your concentrate.

Note: In order to select your concentrate from the list, it must have been previously entered in the Enter Conc screen. This screen can be found by pressing the OPTIONS screen button.

   Press the [CONFIRM] key to select your concentrate and the screen will return to the CALIBRATE CONDUCTIVITY CELL(S) screen.

2. Connect the red and blue concentrate connectors to concentrate solutions as in normal dialysis operation.

3. Remove the dialysate lines from the shunt and connect them to an external conductivity meter. Close the shunt door.

Note: If using the Automata Neo-1 meter, attach the ground strap per the manufacturer's instructions.

Press the [CONFIRM] key to start the calibration. The screen will change.

4. Wait until the conductivity value is stable. When conductivity is stable, the screen will change.

5. Once the conductivity is stable and the screen has changed, select the Conductivity data button.

   Adjust the value shown for Conductivity until it matches the reading on the external conductivity meter and then press the [CONFIRM] key.

6. Press the [CONFIRM] key again and the screen will change.

7. The machine is now adjusting to its first reference point of conductivity for the post conductivity cell. When the reference conductivity is stable, the screen will change.

8. The machine is now adjusting to a second reference point of conductivity for the post conductivity cell. When the conductivity is stable again, the screen will change.

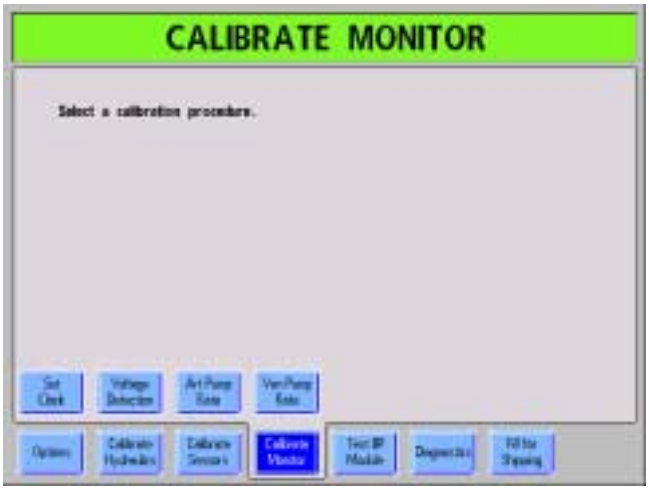
   Press the [CONFIRM] key to save the data. The screen will change.

   Disconnect the conductivity meter and replace the dialysate lines in the shunt.

   Press the [CONFIRM] key to complete the calibration and return to the Calibrate Sensors screen.

2.4 MONITOR CALIBRATION PROCEDURES

From the Service Mode screen, select the Calibrate Monitor screen button. The following screen will appear showing the four monitor calibrations:

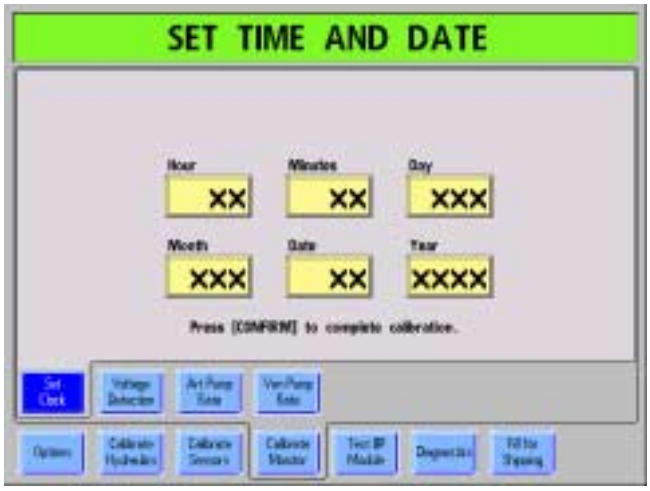


Select one of the following calibrations by touching the appropriate calibration screen button.

- Set Clock
- Voltage Detection
- Arterial Pump Rate
- Venous Pump Rate

2.4.1 SET CLOCK

From the Calibrate Monitor screen, select the Set Clock screen button. The screen will change to the following:

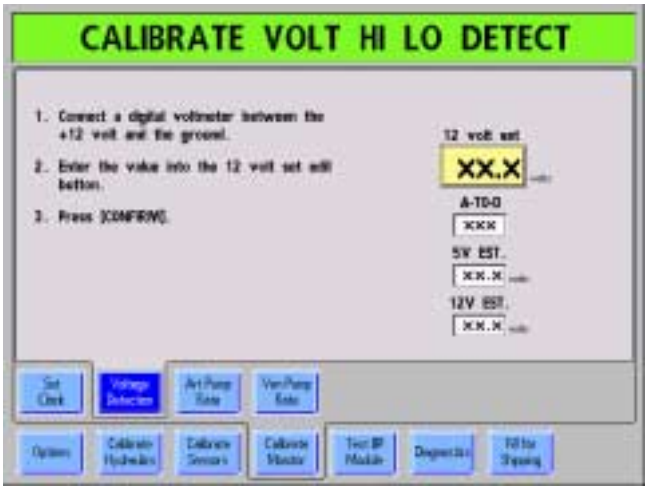


Set each value as follows:

- Select the data button for the value to be changed.
- Set the correct value.
- Press the [CONFIRM] key.
- Repeat for any data button that needs to be changed.
- When all of the data has been entered, press the [CONFIRM] key to return to the Calibrate Monitor screen.

2.4.2 VOLTAGE DETECTION CALIBRATION

From the Calibrate Monitor screen, select the Voltage Detection screen button. The screen will change to the following:



1. Open the monitor unit and connect a Digital Voltmeter between the +12 volt test and the ground test points shown in Figure 7.

2. Select the 12 volt set data button.

   Set the 12 volt set value to the voltage shown on the digital voltmeter, then press the [CONFIRM] key.

3. Press the [CONFIRM] key again and the screen will change.

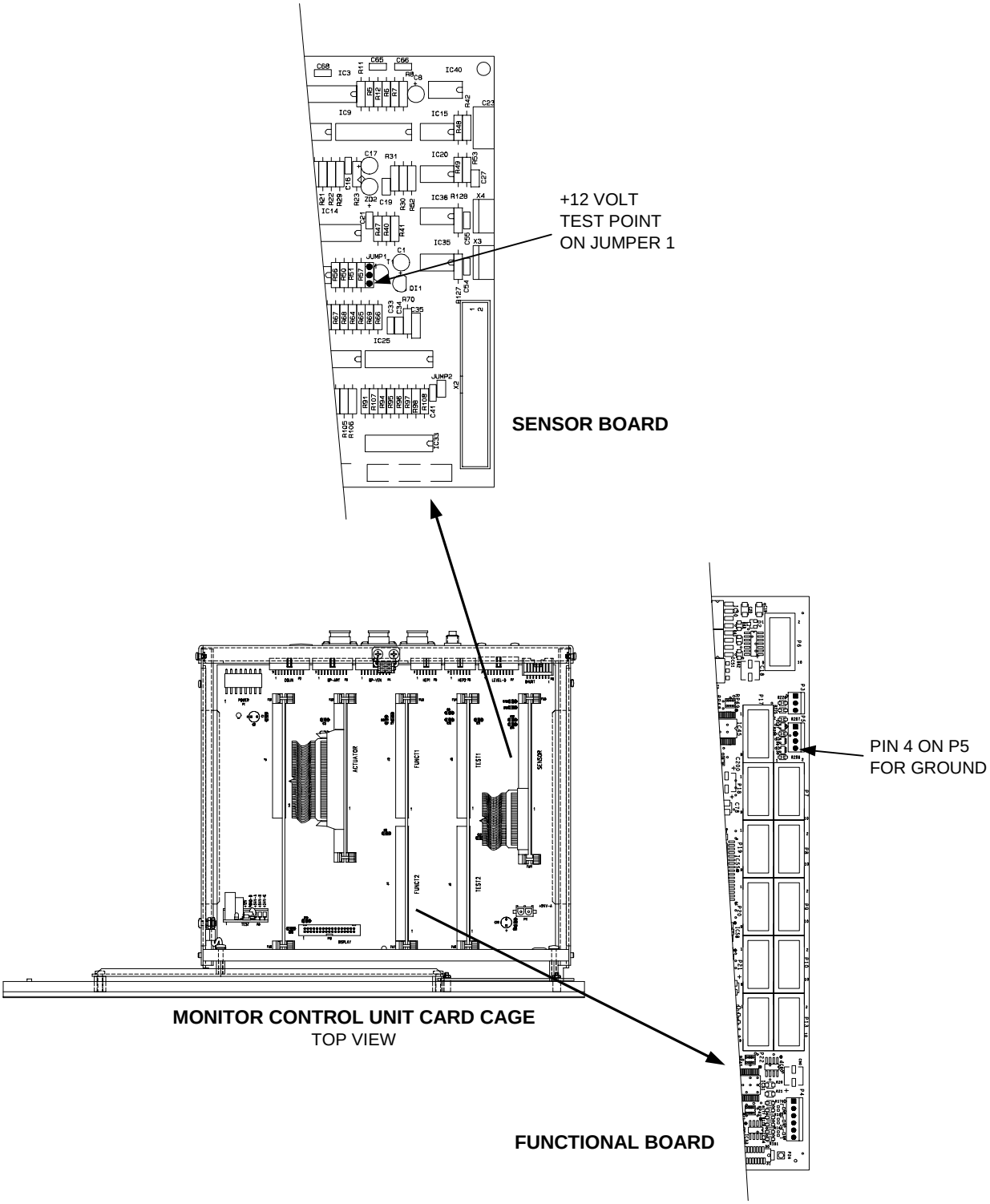
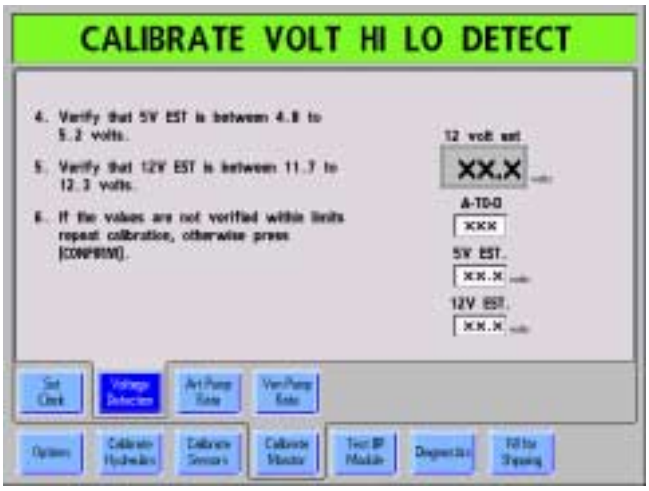


Figure 7. +12 Volt and Ground Test Points.

The screen will display:


CALIBRATE VOLT HI LO DETECT
4. Verify that 5V EST is between 4.8 to 5.2 volts.
5. Verify that 12V EST is between 11.7 to 12.3 volts.
6. If the values are not verified within limits repeat calibration, otherwise press [CONFIRM].
12 volt set
XX.X
A-TO-D
XXX
5V EST.
XX.X
12V EST.
XX.X

4. Verify that the 5V EST. displayed on the screen is between 4.8 and 5.2 volts.

5. Verify that the 12V EST. displayed on the screen is between 11.7 and 12.3 volts.

Note: If the values are not within limits, repeat the Voltage Detection calibration.

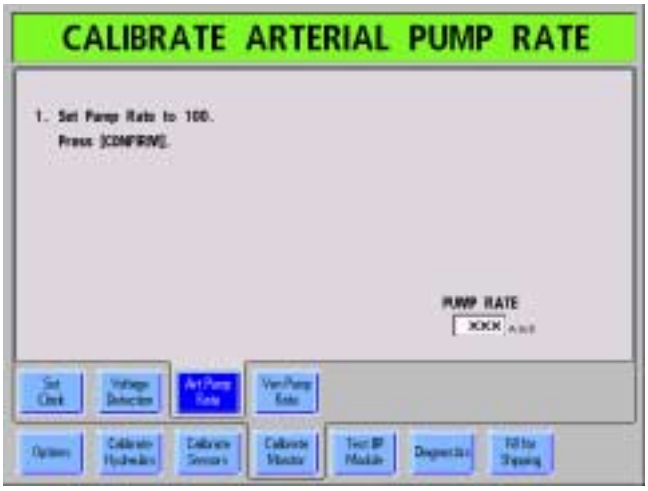
6. If the values are within limits, press the [CONFIRM] key to save the data. The screen will change.

   Disconnect the Digital Voltmeter and close the monitor unit.

   Press the [CONFIRM] key to complete the calibration and return to the Calibrate Monitor screen.

2.4.3 ARTERIAL PUMP RATE

From the Calibrate Monitor screen, select the Art Pump Rate screen button. The screen will change to the following:



1. Adjust the arterial pump rate to 100ml/min.

   Press the [CONFIRM] key and the screen will change.

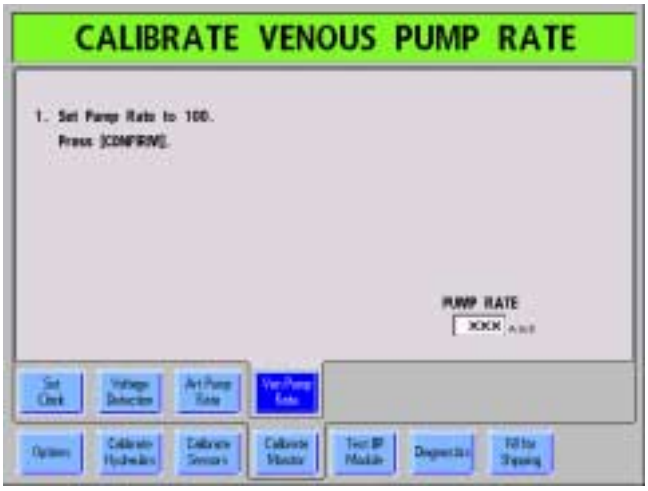
2. Adjust the arterial pump rate to 400ml/min.

   Press the [CONFIRM] key to save the data. The screen will change.

3. Press the [CONFIRM] key again to complete the calibration and return to the Calibrate Monitor screen.

2.4.4 VENOUS PUMP RATE

From the Calibrate Monitor screen, select the Ven Pump Rate screen button. The screen will change to the following:



1. Adjust the venous pump rate to 100ml/min.

   Press the [CONFIRM] key and the screen will change.

2. Adjust the venous pump rate to 400ml/min.

   Press the [CONFIRM] key to save the data. The screen will change.

3. Press the [CONFIRM] key again to complete the calibration and return to the Calibrate Monitor screen.

3.0 CALIBRATION PROCEDURES NOT PERFORMED IN SERVICE MODE

The following procedures are performed with the machine in normal (not Service mode) operation (see Section 1.2).

Caution: Verify that the machine power is Off before changing the position of the SERVICE mode switch on the back of the Monitor Control Unit. Failure to do so may cause calibration data to be lost.

3.1 INLET WATER PRESSURE REGULATOR CALIBRATION

1. Turn off the machine.
2. Shut off the water supply to the machine.
3. Insert a pressure gauge in the water line at the outlet of water inlet pressure regulator #61 (See Figure 1, pg. 5).

Caution: Use tie wraps or tubing clamps to secure the connections. The water pressure may be sufficient to blow the lines off of the gauge if they are not secured.

4. Turn the water supply to the machine On.
5. Turn the machine On.
6. With the dialysate lines in the shunt, select Dialysis mode and start the dialysate flow. The pressure gauge will cycle between two readings as water inlet valve opens and closes.

7. On regulator #61, loosen the lock nut around the adjustment screw (See Figure 1, pg. 5). Use a 5mm Allen wrench to adjust the regulator for a peak pressure of between 18 and 20 psi when water inlet valve 41 is closed.

Note: The gauge must indicate a minimum pressure greater than 8 psi when valve 41 is open. If not, the treated water supply may not meet specifications for flow and pressure.

---

8. Tighten the lock nut and verify the peak pressure is still between 18 and 20 psi on the gauge.

9. Turn the machine Off, turn off the source water supply, remove the gauge and reconnect the tubing using clamps to prevent leaks.

10. Turn the treated water supply source On, turn the machine On and select Dialysis mode. Start dialysate flow and inspect all hoses and connections for leaks.

3.2 LEVEL DETECTOR CALIBRATION

1. Place the machine in Dialysis mode and clear all blood alarms.

2. Insert a venous chamber filled with warm water into the level detector.

Warning! For accurate calibration, use a venous chamber identical to that normally used in the machine.

3. Move the jumper on the LP241/LP450 board to the Calibrate position (see Figure 8).

4. Observe the Channel 1 LED (see Figure 8). If the LED is On, turn channel 1 potentiometer (see Figure 8) clockwise until the LED turns off.

5. Slowly turn channel 1 potentiometer counter-clockwise until the channel 1 LED switches on. Stop turning immediately, just past the point where the LED lights.

6. Repeat Steps 5 and 6 for the Channel 2 LED, adjusting channel 2 potentiometer (see Figure 8). The response of channel 2 is slower than channel 1. When adjusting to the switch point, move the potentiometer in small steps and wait to see if the LED switches on.

7. Move the jumper back to the Normal position (see Figure 8).

8. Press the [RESET] key to clear the alarm and check that both LED's are off, indicating that the Level Detector is sensing no air present in the venous chamber.

9. Remove the venous chamber and watch the LED's. Verify that channel 1 lights first followed quickly by channel 2.

Note: Channel 1 stops the blood pump and Channel 2 clamps the venous blood line.

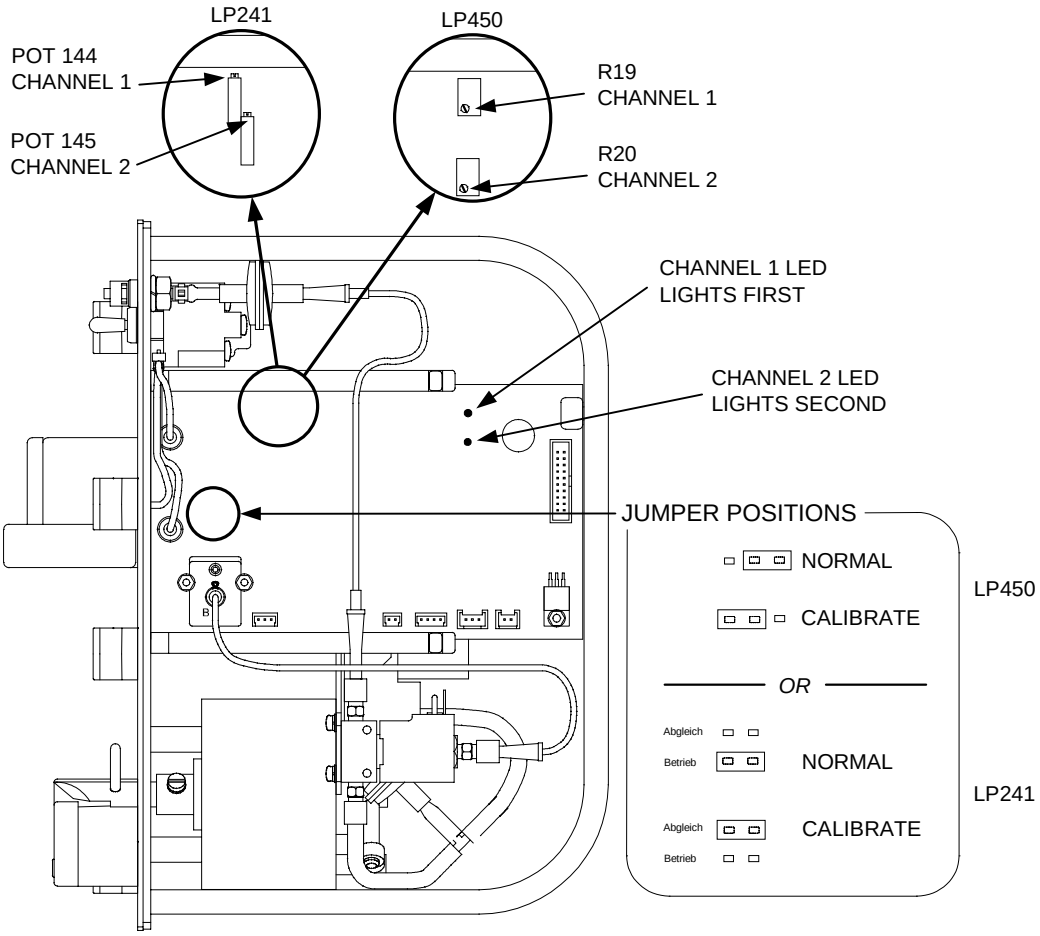


Figure 8. Level Detector Calibration Adjustments.

3.3 BLOOD PUMP CALIBRATION

The speed control circuit on a K blood pump consists of a feedback circuit that monitors the motor speed and automatically adjusts to compensate for any speed fluctuations. There are no adjustments or calibrations on this circuit.

NOTES:

NOTES:

COMMON CONVERSIONS

PRESSURE

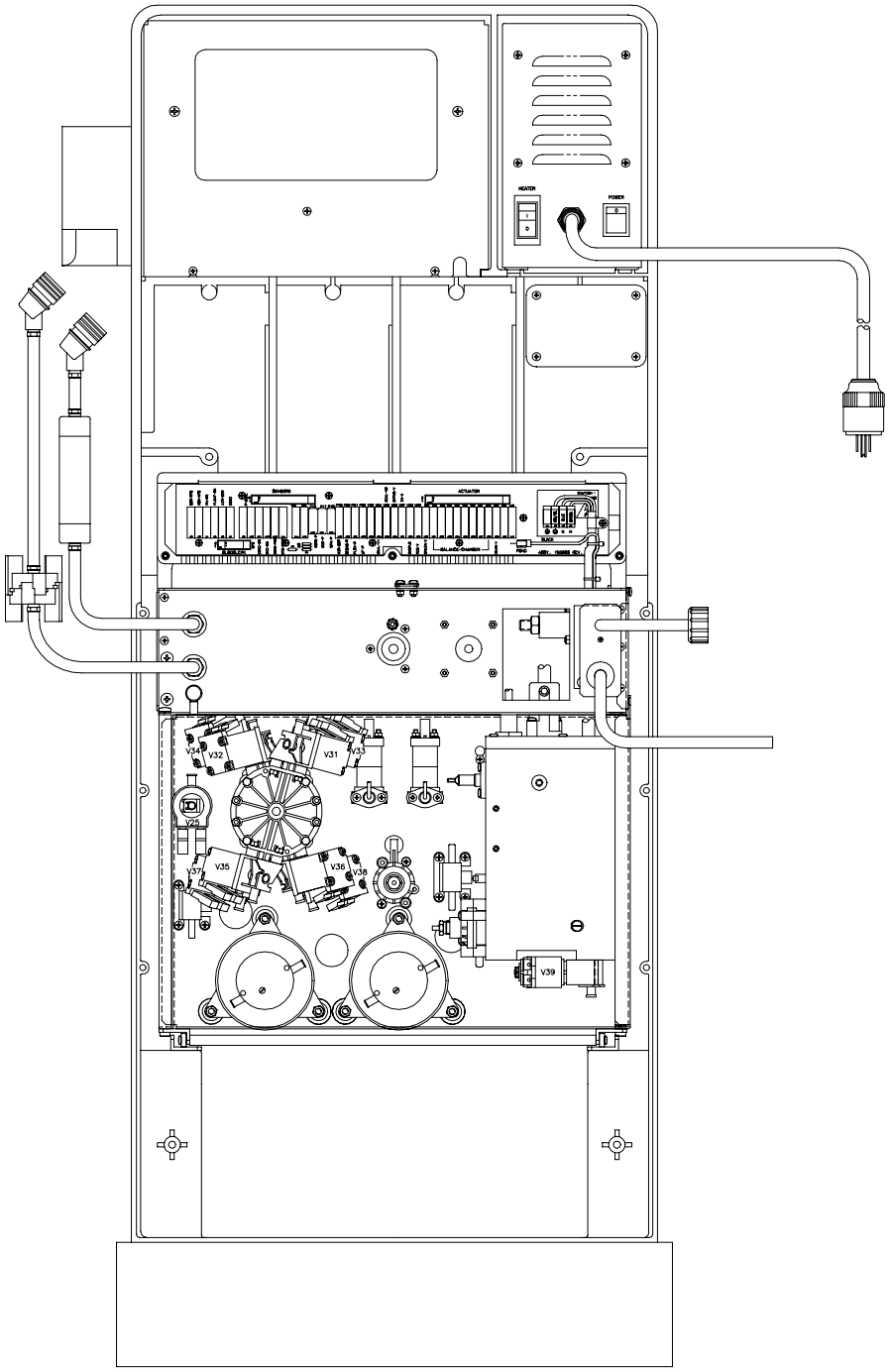
1 Bar	29.53 inHg
1 inHg	25.4 mmHg
1 Psi	51.72 mmHg

VOLUME

1 FLUID OUNCE	26.6 MILLILITERS
1 U.S QUART	0.946 LITERS
1 U.S. GALLON	3.8 LITERS
0.034 FLUID OUNCES	1 MILLILITER
1.057 QUARTS	1 LITER
0.26 U.S. GALLON	1 LITER

MASS

1 OUNCE (avdp.)	28.35 GRAMS
1 POUND (avdp.)	0.45 KILOGRAM
0.035 OUNCE (avdp.)	1 GRAM



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2008K INSTALLATION CHECKLIST INSTRUCTIONS

Written By:	Reviewed By:	Approved By:	Effective Date:
J. Fox	R. Hassard	ECO# 7131	4/18/00

Distribution: Nat'l Svc Mgr (M. Lowery), TS Mgr (K. Cogswell), QSRA (M. Owen), QE (R. Fox), Eng (D.Gavin), Tng (B. Hassard)

PURPOSE:

The purpose of these instructions is to outline the process of installing a 2008K Hemodialysis machine.

EQUIPMENT NEEDED:

Digital Volt Meter, Electrostatic Kit, Temperature/Conductivity meter and hydraulic pressure gauges. **WARNING:** ***Use recommended ESD procedures when handling electronic devices.***

PROCEDURES:

Use form P/N 490051 INSTALLATION CHECKLIST. Complete the upper information section completely, this includes unit name and address, machine serial number, all software versions, shipping damage and record any discrepancies with the shipped accessories.

Line 1 **SET THE K BLOOD PUMP DIPSWITCHES:** With the machine power OFF, locate the dipswitches on the LP955 blood pump board. Set the dipswitches uses Table 1 as reference.

Dip Switch	Description
1	ON for future use
	OFF for use on the 2008K machine.
2	ON for Pre-Pump Arterial Pressure displays (-280 to +300 mmHg)
	OFF for Post-Pump Arterial Pressure display (-80 to +500 mmHg)
3	Not Used
4	ON for Blood pump stop alarm after 30 seconds.
	OFF for Blood pump stop alarm after 15 seconds.
5	Not Used
6	Not Used
7	Not Used
8	ON for tubing diameter selections 2 to 10mm (0.2mm increments)
	OFF for tubing diameter selections 2.6, 4.8, 6.4 and 8.0mm only

Table 1

Line 2 **RINSE MACHINE WITH HEATER OFF:** Insert the acid and bicarb connectors into the ports on front of machine and place dialysate connectors into the shunt. Power the machine ON and wait for the startup screen to appear. Verify that the heater circuit breaker on the back of the power supply is in the OFF position. On the startup screen, press the Rinse button. Allow the machine to complete the rinse cycle (minimum 30 minutes). Record the rinse completion on the Installation Checklist.

Line 3 Obtain the desired option settings from the facility management. Record this information on lines A through FF of the Installation Checklist and proceed to set them as follows:

With the machine OFF set the service switch on the back of the machine into the service position. Turn the machine ON using the power switch on the front panel and wait for the Service Mode screen to appear.

TREATMENT OPTIONS SCREEN:

From the Service Mode screen, press the Options screen button then the Treatment Options button.

Line A: **FORCED TEST:** This option is used to enable or disable the automatic test the machine conducts as soon as all alarms are cleared in dialysis mode prior to connecting a patient. This setting will toggle from Yes to No by pressing the Forced Test button. Once the option is set press the [CONFIRM] key and the X will change from gray to blue. Select Yes or No as dictated by facility management. Record this setting on Installation Checklist.

Line B: **SPREAD LIMITS:** This option is used to enable or disable the ability of the operator spreading the arterial and venous limit by pressing and holding the [Override] key. This setting will toggle from Yes to No by pressing the Spread Limits button. Once the option is set press the [CONFIRM] key and the X will change from gray to blue. Select Yes or No as dictated by facility management. Record this setting on Installation Checklist.

Line C: **AUTO BP READING:** This option is used to select when a blood pressure reading will be read. This setting will toggle from Clock to Interval by pressing the Auto BP Reading button. If Clock is selected, a blood pressure will be taken every quarter of an hour. If Interval is selected, a blood pressure will be taken at a specified period of time. Once the option is set press the [CONFIRM] key and the X will change from gray to blue. Select Clock or Interval as dictated by facility management. Record this setting on Installation Checklist.

Line D: **ALLOW SLOW FLOW:** This option is used to enable or disable the 100 and 200 ml/min dialysate flows. This setting will toggle from Yes to No by pressing the Allow Slow Flow button. Once the option is set press the [CONFIRM] key and the X will change from gray to blue. Select Yes or No as dictated by facility management. Record this setting on Installation Checklist.

NOTE: This option is to be activated only when 100 or 200 ml/min dialysate flow rates are going to be used. If these flows are to be used, the temperature must be recalibrated.

Line E: **EXT PRE-RINSE:** This option is used to enable or disable the extended pre-rinse function. This setting will toggle from Yes to No by pressing the Ext Pre-Rinse button. If this option is set to Yes, the hot rinse pre-rinse is changed from 7 minutes to 20 minutes. Once the option is set press the [CONFIRM] key and the X will change from gray to blue. Select Yes or No as dictated by facility management. Record this setting on Installation Checklist.

Line F: **ALARM AT SVS END:** This option is used to enable or disable an alarm at the completion of an SVS program. This setting will toggle from Yes to No by pressing the Alarm at SVS end button. Once the option is set press the [CONFIRM] key and the X will change from gray to blue. Select Yes or No as dictated by facility management. Record this setting on Installation Checklist.

Line G: **ARTERIAL WIDTH:** This option is used to select the type of arterial pressure alarm limit window. By pressing the Arterial Width button, a selection menu appears. Used the [▲] and [▼] keys to select one of the following choices as dictated by facility management:

User Selectable	The width of the arterial alarm window is not fixed and can be changed by the user on the Test & Options screen during dialysis.
120	Arterial alarm window fixed at a width of 120mmHg.
160	Arterial alarm window fixed at a width of 160mmHg.
200	Arterial alarm window fixed at a width of 200mmHg.

Line H: **VENOUS WIDTH:** This option is used to select the type of venous pressure alarm limit window. By pressing the Venous Width button, a selection menu appears. Used the [▲] and [▼] keys to select one of the following choices as dictated by facility management:

User Selectable	The width of the venous alarm window is not fixed and can be changed by the user on the Test & Options screen during dialysis.
100 Asymetric	Venous alarm window fixed at a width of 100mmHg and the lower limit is at 25mmHg below the actual value after the pressure settles within 1 minute.
120	Venous alarm window fixed at a width of 120mmHg.
160	Venous alarm window fixed at a width of 160mmHg.
200	Venous alarm window fixed at a width of 200mmHg.

Line I: **ACID ALERT DEFAULT:** This option is used to set the acid alert default volume. To change this setting, select the Acid Alert Default data button then use the [▲] and [▼] keys to select the desired volume from 0 to 9.9 liters. When the desired amount has been reached, press [CONFIRM] key. Record this setting on the Installation Checklist.

Line J: **BIC ALERT DEFAULT:** This option is used to set the bicarbonate alert default volume. To change this setting, select the Bic Alert Default data button then use the [▲] and [▼] keys to select the desired volume from 0 to 9.9 liters. When the desired amount has been reached, press [CONFIRM] key. Record this setting on the Installation Checklist.

Line K: **PRIME AMOUNT:** This option is used to set the priming volume used during prime. To change this setting, select the Prime Amount data button then use the [▲] and [▼] keys to select the desired volume from 0 to 1000ml. When the desired amount has been reached, press [CONFIRM] key. Record this setting on the Installation Checklist.

Line L: **RECIRCULATE:** This option is used to enable or disable the recirculation function. This setting will toggle from Yes to No by pressing the Recirc Option button. Once the option is set press the [CONFIRM] key and the X will change from gray to blue. Select Yes or No as dictated by facility management. Record this setting on Installation Checklist. If this option is set to Yes, perform the following:

- **RECIRC GOAL:** Set the recirculation goal by selecting the Recirc Goal data button then use the [▲] and [▼] keys to select the desired volume from 10 to 9990ml. When the desired amount has been reached, press [CONFIRM] key. Record this setting on the Installation Checklist.

- **RECIRC TIME:** Set the recirculation time by selecting the Recirc Time data button the use the [▲] and [▼] keys to select the desired volume from 0 min to 9 hrs 59 min. When the desired amount has been reached, press [CONFIRM] key. Record this setting on the Installation Checklist.

HARDWARE OPTIONS SCREEN:

From the Service Mode screen, press the Options screen button then the Hardware Options button.

Line M: **ONLINE PHT:** This option is used to enable or disable the online pressure holding test option. This setting will toggle from Yes to No by pressing the Online PHT button. Once the option is set press the [CONFIRM] key and the X will change from gray to blue. Select Yes or No as dictated by facility management. Record this setting on Installation Checklist.

Line N: **ART CHAMBER:** This option is used to select for a prepump or a postpump arterial chamber tubing configuration. This setting will toggle from Pre to Post by pressing the Art Chamber button. Once the option is set press the [CONFIRM] key and the X will change from gray to blue. Select Pre or Post as dictated by facility management. Note: Dipswitch #2 on the blood pump must agree with this setting. Record this setting on Installation Checklist.

Line O: **MAX UF RATE:** This option is used to set the maximum allowable ultrafiltration rate selectable by the user. To change this setting, select the Max UF Rate data button then use the [▲] and [▼] keys to select the desired volume from 1000, 2000, 3000, or 4000ml/hr. When the desired amount has been reached, press [CONFIRM] key. Record this setting on the Installation Checklist.

Line P: **AUDIBLE ALARM:** This option is used to enable or disable audible alarm when the lines are off the shunt. This setting will toggle from Yes to No by pressing the Audible Alarm button. If Yes is selected, audible alarms will be heard when the lines are off the shunt. If No is selected, no audible alarms will be heard when the lines are off the shunt and no blood is sensed.

NOTE: If blood is sensed, audible alarms will be heard regardless of the Audible Alarm option setting.

Once the option is set press the [CONFIRM] key and the X will change from gray to blue. Select Yes or No as dictated by facility management. Record this setting on Installation Checklist

Line Q: **T&C MODE:** This option is not used during the machine installation process and must always have NO selected before the machine is released for use.

Line R: **0 ART LIMIT:** This option is used to select if the upper arterial alarm limit is moved to –15mmHg when blood is sensed. This setting will toggle from Yes to No by pressing the 0 Art Limit button. If Yes is selected, the upper arterial alarm limit will move to –15mmHg when blood is sensed. If No is selected, the upper arterial alarm limit will NOT move to –15mmHg when blood is sensed. Once the option is set press the [CONFIRM] key and the X will change from gray to blue. Select Yes or No as dictated by facility management. Record this setting on Installation Checklist.

Line S: **OFF AFTER HEAT DISIN:** This option is used to select if the machine will power off after a heat disinfect program. This setting will toggle from Yes to No by pressing the Off after Heat Disin button. If Yes is selected, the machine will power off after a heat disinfect program. If No is selected, the machine will NOT power off after a heat disinfect program. Once the option is set press the [CONFIRM] key and the X will change from gray to blue. Select Yes or No as dictated by facility management. Record this setting on Installation Checklist.

Line T: **FDS08 BEACON:** This option is used to enable or disable the communication between the FDS08 system and the Beacon. This setting will toggle from Yes to No by pressing the FDS08 Beacon button. If Yes is selected, the Beacon lights will be controlled by the FDS08 system. If No is selected, the Beacon lights will be controlled by the color of the 2008K status box. Once the option is set press the [CONFIRM] key and the X will change from gray to blue. Select Yes or No as dictated by facility management. Record this setting on Installation Checklist.

Line U: **USE CMS208K:** This option is used to enable or disable the communication with the CMS208K system. This setting will toggle from Yes to No by pressing the Use CMS208K button. Once the option is set press the [CONFIRM] key and the X will change from gray to blue. Select Yes or No as dictated by facility management. Record this setting on Installation Checklist.

Line V: **BVM:** This option is used to enable or disable the use of the blood volume monitor option. This setting will toggle from Yes to No by pressing the BVM button. Once the option is set press the [CONFIRM] key and the X will change from gray to blue. Select Yes or No as dictated by facility management. Record this setting on Installation Checklist.

Line W: **CLEARANCE:** This option is used to enable or disable the online clearance option. This setting will toggle from Yes to No by pressing the Clearance button. Once the option is set press the [CONFIRM] key and the X will change from gray to blue. Select Yes or No as dictated by facility management. Record this setting on Installation Checklist.

Line X: **DIASAFE® FILTER:** This option is used to enable or disable the DIASAFE® filter option. This setting will toggle from Yes to No by pressing the Diasafe Filter button. Once the option is set press the [CONFIRM] key and the X will change from gray to blue. Select Yes or No as dictated by facility management. Record this setting on Installation Checklist.

Line Y: **HEPARIN PUMP:** This option is used to enable or disable the digital heparin pump option. This setting will toggle from Yes to No by pressing the Heparin Pump button. Once the option is set press the [CONFIRM] key and the X will change from gray to blue. Select Yes or No as dictated by facility management. Record this setting on Installation Checklist.

Line Z: **BTM:** This option is used to enable or disable the use of the blood temperature monitor option. This setting will toggle from Yes to No by pressing the BTM button. Once the option is set press the [CONFIRM] key and the X will change from gray to blue. Select Yes or No as dictated by facility management. Record this setting on Installation Checklist.

COMM OPTIONS SCREEN:

The communication option screen is not used during the installation process.

RINSE TIMES SCREEN:

From the Service Mode screen, press the Options screen button then the Rinse Times button.

NOTE: - Rinse time should not be set to less than 15 minutes.
- Heat Disinfect should not be set to less than 20 minutes.

Line AA **ACID CLEAN:** Select the Acid Clean data button then use the [▲] and [▼] keys to select the desired program time. When the desired program time has been reached, press the [CONFIRM] key. Record this setting on the Installation Checklist.

Line BB **HEAT DISINFECT:** Select the Heat Disinfect data button then use the [▲] and [▼] keys to select the desired program time. When the desired program time has been reached, press the [CONFIRM] key. Record this setting on the Installation Checklist.

Line CC **RINSE:** Select the Rinse data button then use the [▲] and [▼] keys to select the desired program time. When the desired program time has been reached, press the [CONFIRM] key. Record this setting on the Installation Checklist.

Line DD **CHEMICAL/RINSE:** Select the Chemical/Rinse data button then use the [▲] and [▼] keys to select the desired program time. When the desired program time has been reached, press the [CONFIRM] key. Record this setting on the Installation Checklist.

Line EE **CHEMICAL/DWELL:** Select the Chemical/Dwell data button then use the [▲] and [▼] keys to select the desired program time. When the desired program time has been reached, press the [CONFIRM] key. Record this setting on the Installation Checklist.

ENTER CONC SCREEN:

From the Service Mode screen, press the Options screen button then the Enter Conc button.

Line FF: **CONCENTRATE TYPE:** Determine the concentrate type and numbers from the acid containers at the unit (Fresenius, Cobe, Drake "salt spiked", or Acetate).

SELECT CONCENTRATE TYPE

To select the type of concentrate press the Change Type button on the Enter Conc screen. A selection menu will appear. Use the [▲] and [▼] keys to select the concentrate type dictated by the facility management then press the [CONFIRM] key. Record the concentrate type on the Installation Checklist.

ADDING CONCENTRATE FROM CATALOG

A list of concentrates must be constructed so they are available to the user on the Dialysate screen. By pressing the Add From Catalog button on the Enter Conc screen, a catalog list of concentrates appears in a selection menu. Use the [▲] and [▼] keys to select a concentrate from the catalog list then press the [CONFIRM] key. The screen returns to the Enter Conc screen and now shows a user list with the selected concentrate. If additional concentrates are to be used, press the Add From Catalog button again and select another concentrate. When the [CONFIRM] key is pressed the screen will update the user list with the additional concentrate. Repeat this operation until all concentrates (maximum 10) used by the unit have been entered. If a concentrate is not in the catalog list, refer to the next section.

ADDING A CONCENTRATE NOT ON CATALOG LIST

If a concentrate is not on the catalog list, it can be added to the user list by press the Add New button on the Enter Conc screen. Once the Add New button is pressed, a concentrate component screen will appear. On this screen the naming of the concentrate and concentrate components can be entered.

A unique name must be given to the new concentrate so that it can be identified in the user list. To name the new concentrate, press the Conc Name button. A keyboard will appear on the screen. Use the screen keyboard and the number keys on the front panel to create a unique name (up to 7 characters) for the concentrate being added. Once the name has been typed in, press the [CONFIRM] key to return to the concentrate component screen. Verify the new concentrate name appears next to the Conc Name button.

If the new concentrate is a Granuflo type, press the Granuflo button to toggle X from No to Yes then press the [CONFIRM] key. The X will change from gray to blue.

The new concentrate must have its components specified. From the label of the new concentrate, determine the value for the Sodium (Na+), Potassium (K+), Calcium (Ca++), Magnesium (Mg++), Acetic Acid, and Dextrose. Enter each value by selecting the appropriate data button and use the [▲] and [▼] keys to change the value then press the [CONFIRM] key. Once these values have been entered, the values for chloride (Cl-) and Sodium Acetate (Na Acetate) will be calculated.

NOTE: If the new concentrate is Acetate, determine the value for the Sodium (Na+), Potassium (K+), Calcium (Ca++), Magnesium (Mg++), Acetate, and Dextrose. The calculated values are chloride (Cl-) and Acetic Acid.

If all of the concentrate components were entered correctly, the chloride value will match the concentrate label.

DELETING CONCENTRATE FROM USER LIST

To delete a concentrate from the user list, press the Del From List button on the Enter Conc screen. The user list of concentrates will appear. Use the [▲] and [▼] keys to select the concentrate to be deleted then press the [CONFIRM] key.

TRANSFER DATA SCREEN:

This screen is used to transfer concentrate data between 2008K machines using the RS232 serial port.

CAUTION: Do not attempt to transfer concentrate data from a 2008H machine to a 2008K machine nor from a 2008K to a 2008H machine.

1. Power must be OFF on both 2008K machines.
2. Pull out the cardcages of both machines involved in the data transfer.
3. Reposition the cable connected at P6 of the Functional board to F9 on both machines
4. Connect cable P/N 150394 to the RS232 ports of the source machine and the destination machine.
5. Turn both machines ON using the power switch on the front panel and wait for the Service Mode screen to appear.
6. From the Service Mode screen on the destination machine, press the Options screen button then the Transfer Data button. On the Transfer Data screen press the Receive Data button.
7. From the Service Mode screen on the source machine, press the Options screen button then the Transfer Data button. On the Transfer Data screen press the Transmit Data button.
8. When the destination machine displays SUCCESS, the data transfer is complete. If SUCCESS does not appear within 20 seconds, check all cable connections and repeat the process.
9. Upon completion, power the machines OFF and reconnect the cable from P9 to P6 on the Functional boards.

UF PROFILING SCREEN:

This option screen is not used during the installation process.

Line 4 **CHECK ALL HYDRAULIC PRESSURES.**

INLET WATER PRESSURE REGULATOR CHECK

Verify the inlet water pressure regulator provides the proper water pressure as follows:

1. With the machine running in dialysis mode, turn OFF the flow by pressing the [Dialysate Flow on/off] key.
2. Shut off the water supply to the machine.
3. Install a gauge with a T-fitting to monitor the pressure at the outlet side of the Inlet Pressure Regulator. Use tie wraps or tubing clamps to secure the connections. The water pressure may be sufficient to blow the lines off the fittings if they are not secured.
4. Turn the water supply to the machine ON.
5. With the dialysate lines in the shunt, turn the dialysate flow back ON by pressing the [Dialysate Flow on/off] key. The pressure gauge will cycle between two readings as the water inlet valve opens and closes.
6. Verify that the pressure gauge reads between 18 and 20 psi when the pressure is at its highest value, and reads greater than 8 psi when the pressure is at its lowest value.

NOTE: Readings below 8 psi at the lowest level indicates inadequate inlet water flow into the machine. This may be caused by a dirty inlet filter screen or problems with the treated water supply.

7. Turn the machine OFF, then turn the water supply OFF. Remove the gauge and reconnect the tubing using clamps to prevent leaks.
8. Turn the water supply ON, turn the machine ON and select Dialysis mode. Inspect all hoses and connections to ensure that there are no leaks.

NOTE: Calibration must be performed if the inlet water pressure regulator is not within tolerance.

DEAERATION & LOADING PRESSURE CHECKS

Verify that the deaeration pressure is between -24 and -25 inHg and the loading pressure is between 18 and 20 psi (between 23 and 25 psi if a DIASAFE® filter system is installed) as follows:

1. With the machine running in dialysis mode, turn OFF the flow by pressing the [Dialysate Flow on/off] key.
2. Install a pressure gauge with a T-fitting to monitor the pressure on the inlet (suction) side of the deaeration pump.
3. Connect a pressure gauge equipped with a yellow connector into the red Acetate/Acid port.
4. Press the [Dialysate Flow on/off] key to turn the dialysate flow back ON.
5. DEAERATION PRESSURE: Verify that the pressure gauge on the deaeration pump indicates between -24 and -25 inHg. This measurement will be difficult since the needle will be vibrating. Therefore, verify that it does not go higher than -24 inHg or lower than -25 inHg.
   LOADING PRESSURE: Verify that the pressure gauge in the Acetate/Acid port indicates between 18 and 20 psi (between 23 and 25 psi if a DIASAFE® filter system is installed).

NOTE: Calibration must be performed if the deaeration or loading pressures are not within tolerance.

FLOW RELIEF PRESSURE CHECK

Verify that the flow relief pressure is between 29 and 30 psi (between 35 and 36 psi if a DIASAFE® filter system is installed) as follows:

1. With the machine running in dialysis mode and at the Home screen, turn OFF the flow by pressing the [Dialysate Flow on/off] key.
2. Install a pressure gauge with a T-fitting to monitor the pressure on the output side of the flow pump.
3. Press the [Dialysate Flow on/off] key to turn the dialysate flow back ON. Set the flow to 800 ml/min.
4. Clamp the outlet tubing of the flow pump after the gauge. Verify the gauge indicates between 29 and 30 psi (between 35 and 36 psi if a DIASAFE® filter system is installed).
5. Unclamp the tubing, turn the flow OFF and remove the pressure gauge.

NOTE: Calibration must be performed if the flow relief pressure is not within tolerance.

Line 5 **CHECK DIALYSATE PRESSURE.**

1. With the machine in dialysis mode and at the Home screen, open the shunt door and remove the dialysate lines.
2. Connect the dialysate lines to a four-way connector and hang it at normal dialyzer height.
3. Connect a 30cc syringe to one of the four-way connector outlets.
4. Connect an external pressure gauge to the remaining four-way connector outlet.
5. Clamp the tubing between the external pressure gauge and the four-way connector.
6. Close the shunt door.
7. Dialysate should be flowing, as indicated by the flow indicator in the dialysate lines. Wait until no air is visible passing through the flow indicator then press the [Dialysate Flow on/off] key to stop the flow.
8. Unclamp the tubing between the external pressure gauge and the four-way connector.
9. Use the syringe to create a pressure reading of 0mmHg on the external pressure gauge. Verify that the TMP value on the Home screen is 0mmHg.
10. Use the syringe to create a pressure reading of -250mmHg on the external pressure gauge. While holding this pressure, verify that the TMP value on the Home screen is 250mmHg ± 10mmHg.

NOTE: Calibration must be performed if the TMP values are not within tolerance.

11. Return the dialysate lines to the shunt.
12. Turn the dialysate flow back on by pressing the [Dialysate Flow on/off] key.

Line 6 **CALIBRATE LEVEL DETECTOR WITH UNIT'S BLOOD LINES**

1. Place the machine in Dialysis mode and clear all blood alarms.
2. Insert a venous chamber filled with warm water into the level detector. For accurate calibration, use a venous chamber identical to that normally used in the machine.
3. Move the jumper on the LP241 board to the Calibrate position.
4. Observe the Channel 1 LED. If the LED is ON, turn potentiometer 144 on the LP241 board clockwise until the LED turns OFF.
5. Slowly turn potentiometer 144 counter-clockwise until the channel 1 LED switches ON. Stop turning immediately, just past the point where the LED lights.
6. Repeat Steps 5 and 6 for the Channel 2 LED, adjusting potentiometer 145. The response of channel 2 is slower than channel 1. When adjusting to the switch point, move the potentiometer in small steps and wait to see if the LED switches ON.
7. Move the jumper on the LP241 board back to the Normal position.
8. Press the [RESET] key to clear the alarm and check that both LED's are OFF, indicating that the level detector is sensing no air present in the venous chamber.
9. Remove the venous chamber and watch the LED's. Verify that channel 1 lights first followed quickly by channel 2.

NOTE: Channel 1 stops the blood pump and Channel 2 clamps the venous blood line.

Line 7 **VERIFY VENOUS & ARTERIAL PRESSURE DISPLAYS (ZERO & GAIN).**

Place the machine in Dialysis mode and select the Home screen tab. Clear all blood alarms.

VENOUS PRESSURE CHECK

1. Verify that the venous pressure bargraph indicates 0mmHg when the venous pressure monitor port is open to atmosphere.
2. Attach a syringe and an external pressure gauge to the venous pressure monitor port using a T fitting.
3. Use the syringe to create a pressure reading of 400mmHg on the external pressure gauge. While holding this pressure, verify that the venous pressure bargraph indicates 400mmHg.

NOTE: Calibration must be performed if the venous pressure display values are not within tolerance.

ARTERIAL PRESSURE CHECK

1. Verify that the arterial pressure bargraph indicates 0mmHg when the arterial pressure monitor port is open to atmosphere.
2. Attach a syringe and an external pressure gauge to the arterial pressure monitor port using a T fitting.
3. Use the syringe to create a pressure reading of 200mmHg (400mmHg for a post pump) on the external pressure gauge. While holding this pressure, verify that the arterial pressure bargraph indicates the same value.

NOTE: Calibration must be performed if the arterial pressure display values are not within tolerance.

Line 8: **BLOOD PUMP TUBING DIAMETER:** Determine the diameter size of units blood pump tubing segment. Open the blood pump door. The blood pump display will show the selected tubing diameter. If not correct, press the [▲] and [▼] keys on the blood pump simultaneously. The tubing diameter value will flash. Use the [▲] and [▼] keys to change to the correct tubing diameter. When correct press the [Start/Stop] key to save the setting. The display will stop flashing and the new diameter will be displayed. Record this diameter on the Installation Checklist.

Line 9 **VERIFY UF PUMP STROKE VOLUME = 1cc/STROKE.**

Verify the UF pump volume as follows:

1. Remove the dialysate lines from the shunt and place them in a bucket of water on the floor.
2. Place the machine in Dialysis mode and clear all blood alarms. Press the [Start/Stop] key to start the blood pump.
3. On the Home screen, select the UF Rate data button. Set the UF Rate to 1000ml/hr then press the [CONFIRM] key.
4. Connect the FLUID SAMPLE/ULTRA FILTRATE output tubing to a 25 ml buret. Open the buret stopcock.
5. Press the [UF on/off] key. The green light above the key should light indicating that the UF pump is running and fluid should be pumping into the buret. If the light is flashing, there is a blood alarm or the machine is in a Fill Program. If this is the case, the UF Pump will not run. Correct any conditions as required so the green light does not flash.

NOTE: If the UF pump does not provide output even though the green light is on and not flashing, inspect the UF check valves. If a check valve is installed backwards, the pump will not work.

6. When fluid appears in the buret, press the [UF on/off] key to stop the pump. Adjust the amount of fluid in the buret so the meniscus is on the 25ml mark.
7. Press the [UF on/off] key and allow exactly 24 pulses of fluid into the buret, then press the [UF on/off] key again to stop the pump.
8. Measure the amount of fluid collected. The level in the buret should be between 0.90 and 1.10 ml on the buret scale indicating that between 23.90 and 24.10 ml was collected. If the volume collected is not within this range, repeat this test to ensure it is done accurately before considering recalibration or other repairs.

NOTE: Calibration must be performed if the UF pump stroke volume is not within tolerance.

Line 10 **VERIFY CORRECT TEMPERATURE, ACTUAL AND DISPLAYED.**

Verify that the actual dialysate temperature measured by an external meter agrees with the display screen within 0.5 °C at 37 °C and 39 °C as follows:

1. Connect the dialysate lines to an external meter.
2. Place the machine in Dialysis mode with concentrate in the system. Clear any alarms.
3. On the Home screen, select the Temperature data button. The data button label changes to Temp. Set and shows the temperature set point. Use the [▲] and [▼] keys to select a set point of exactly 37.0 and press the [CONFIRM] key. The button label will change back to Temperature and now displays the actual dialysate temperature.
4. Wait until the dialysate temperature stabilizes. It will settle very close to the value set, depending upon inlet water temperature and other conditions.
5. After the temperature of the dialysate stabilizes, compare the temperature shown on the Temperature data button with that shown on the external meter connected to the dialysate lines. The two readings must be within 0.5 degrees of each other.
6. Repeat steps 3, 4 and 5 with the temperature set to 39 °C. Verify that the actual temperature reported on the Temperature data button and the external meter are within 0.5 °C of each other after the temperatures stabilize again.

NOTE: Calibration must be performed if the actual or displayed temperatures are not within tolerance.

Line 11: **BASE SODIUM:** Determine the desired base sodium as dictated by facility management and record the value on the Installation Checklist. Remove the connectors from their ports and connect them into concentrates. Place the machine in dialysis mode and select the Dialysate screen tab. Select the Base Na^+ data button. Use the [▲] and [▼] keys to adjust the value to the desired setting then press the [CONFIRM] key. If more than one concentrate has been entered, a base sodium should be entered for each. Select each concentrate one at a time and adjust their base sodium as described above.

Line 12: **BASE BICARBONATE:** Determine the desired base bicarbonate as dictated by facility management and record the value on the Installation Checklist. Remove the connectors from their ports and connect them into concentrates. Place the machine in dialysis mode and select the Dialysate screen tab. Select the Bicarbonate data button. Use the [▲] and [▼] keys to adjust the value to the desired setting then press the [CONFIRM] key. If more than one concentrate has been entered, a base bicarbonate should be entered for each. Select each concentrate one at a time and adjust their base bicarbonate as described above.

Line 13 **CONDUCTIVITY**

1. Switch to the debug screens by pressing and holding the [▲] and [▼] keys at the same time for approximately 1 sec. The main display will change indicating that the machine is in debug mode.
2. Use the [▲] and [▼] keys to go to debug screen #0.
3. On debug screen #0, locate the ACID and the BIC data boxes. Record the **ACID STEPS** (ACID data box) and **BICARB STEPS** (BIC data box) on the installation Checklist in their appropriate places.
4. On the Dialysate screen, the TCD value is the expected conductivity. Record this value on the Installation Checklist under **EXPECTED**.
5. Verify that the dialysate conductivity measured by the machines internal conductivity cell agrees with an external meter within 0.1 mS/cm as follows:
   a. Connect an external conductivity meter to the dialysate lines.
   b. With the machine in Dialysis mode, out of bypass, and the flow ON, compare the value shown on the external meter with the conductivity shown on the Home screen. They must be within 0.1 mS/cm of each other.
   c. Record **ACTUAL** and **DISPLAYED** conductivity on the Installation Checklist.

Line 14 **VERIFY pH IS APPROX.7.3 -Record pH**

1. Place the machine into dialysis mode and allow it 10 minutes to stabilize.
2. Use a pH test strip (P/N 335130-01 or equivalent) to verify the dialysate fluid is approximately 7.3.
3. Record the measured value on the Installation Checklist.

Line 15 **PERFORM PRESSURE HOLDING TEST AND ALARMS TEST.**

1. Place the machine into dialysis mode and allow it 10 minutes to stabilize.
2. With the machine stable, alarm free and dialysate lines on the shunt, select the Test & Options screen tab. Press the Both Tests button and allow machine to run through the autotest. The Test complete message will be displayed when test is finished.

Line 16 **VERIFY NO RESIDUAL FORMALDEHYDE IN DRAIN FLUID.**

NOTE: This step can only be performed after all previous steps are completed successfully.

1. Place the machine into rinse mode.
2. Open shunt door to stop rinse timer.
3. Allow the machine to rinse for 10 minutes.

NOTE: Prior to this step, the machine must have been in rinse for a minimum of 30 minutes. A positive test will result if the machine is not properly rinsed.

4. Use a formaldehyde test strip (P/N 335130-02 or equivalent) to verify the drain fluid has less than 5 ppm of residual formaldehyde. If 5 ppm or greater is detected, locate source and repair as needed. Once the repair is completed, rinse the machine until the residual formaldehyde results are negative.
5. Record the measured value on the Installation Checklist
6. Pull red connector to interrupt rinse program.

WARNING: A machine with a positive residual formaldehyde test **MUST NOT** be released for use until the source is located and the problem resolved.

Line 17 **HEAT DISINFECT MACHINE.**

Place the connectors into their respective rinse ports and the dialysate lines into the shunt. From the Startup screen, press the Heat Disinfect button. At the conclusion of heat disinfect the machine will either shut off or return to idle mode depending on the option selected on the Hardware Options.

Line 18 **CLEAN EXTERIOR**

Use a damp clean cloth and wipe the machine down.

Line 19 **ATTACH PROPER CONCENTRATE DILUTION LABELS AND ADAPTERS**

Fresenius type:	Install label P/N 450057
Drake "salt spiked" type:	Install label P/N 450009
Cobe type:	Install label and adapter kit P/N 150022

REPAIRS NEEDED

Record any repairs needed, attach CSRR form detailing these repairs.

SIGNATURE SECTION

Record TRAVEL HOURS, and LABOR HOURS. RES should sign and date. CUSTOMER should sign and date. The customer will retain part V, RES retains part IV, all remaining parts of the Installation Checklist should be returned to the Walnut Creek office.

FRESENIUS, USA
2008K INSTALLATION CHECKLIST

S _____
Customer Service Repair Record

***THIS DOCUMENT IS TO BE USED WITH INSTALLATION INSTRUCTIONS, P/N 507300**

UNIT NAME:_____ **SERIAL NUMBER:**_____ **SOFTWARE:**_____ / _____ (FUNCTIONAL / ACTUATOR)

UNIT ADDRESS:_____ **STATE:**_____ **ZIP:**_____

SHIPPING DAMAGE_____

ACCESSORIES PRESENT_____

1. SET THE K BLOOD PUMP DIPSWITCHES _____

2. RINSE MACHINE WITH HEATER OFF (Minimum 30 minutes) _____

3. RECORD THE STATUS OF THE FOLLOWING OPTIONS, AND REQUESTED INFORMATION:

TREATMENT OPTIONS:

A. FORCED TEST **YES** _____ **NO** _____
B. SPREAD LIMITS **YES** _____ **NO** _____
C. AUTO BP READING **CLOCK** _____ **INTERVAL** _____
D. ALLOW SLOW FLOW **YES** _____ **NO** _____
E. EXT PRE-RINSE **YES** _____ **NO** _____
F. ALARM AT SVS END **YES** _____ **NO** _____
G. ARTERIAL WIDTH _____
H. VENOUS WIDTH _____
I. ACID ALERT DEFAULT _____
J. BIC ALERT DEFAULT _____
K. PRIME AMOUNT _____
L. RECIRC OPTION **YES** _____ **NO** _____
RECIRC GOAL _____
RECIRC TIME _____

HARDWARE OPTIONS:

M. ONLINE PHT **YES** _____ **NO** _____
N. ART CHAMBER **PRE** _____ **POST**_____
O. MAX UF RATE _____
P. AUDIBLE ALARM **YES** _____ **NO** _____
Q. T&C MODE Not used during installation

R. 0 ART LIMIT **YES** _____ **NO** _____
S. OFF AFTER HEAT DISIN **YES** _____ **NO** _____
T. FDS08 BEACON **YES** _____ **NO** _____
U. USE CMS208K **YES** _____ **NO** _____
V. BVM **YES** _____ **NO** _____
W. CLEARANCE **YES** _____ **NO** _____
X. DIASAFE® FILTER **YES** _____ **NO** _____
Y. HEPARIN PUMP **YES** _____ **NO** _____
Z. BTM **YES** _____ **NO** _____

COMMUNICATION OPTIONS: Not used during installation

RINSE OPTIONS:

AA. ACID CLEAN _____
BB. HEAT DISINFECT _____
CC. RINSE _____
DD. CHEMICAL/RINSE _____
EE. CHEMICAL/DWELL _____

ENTER CONCENTRATE:

FF. CONCENTRATE TYPE _____

TRANSFER DATA: Refer to P/N 507300

UF PROFILES: Not used during installation.

4. CHECK ALL HYDRAULIC PRESSURES _____

5. CHECK DIALYSATE PRESSURE _____

6. CALIBRATE LEVEL DETECTOR WITH UNIT'S BLOOD LINES _____

7. VERIFY VENOUS & ARTERIAL PRESSURE DISPLAYS (ZERO & GAIN) _____

8. BLOOD PUMP TUBING DIAMETER _____ mm

9. VERIFY UF PUMP STROKE VOLUME = 1cc/STROKE _____

10. VERIFY CORRECT TEMPERATURE, ACTUAL AND DISPLAYED _____

11. BASE SODIUM _____mEq/l

12. BASE BICARB _____mEq/l

13. CONDUCTIVITY: ACID STEPS _____ / BICARB STEPS _____ / EXPECTED _____ / ACTUAL _____ / DISPLAYED _____

14. VERIFY pH IS APPROX. 7.3 - RECORD pH _____

15. PERFORM PRESSURE HOLDING TEST AND ALARM TEST _____

16. VERIFY NO RESIDUAL FORMALDYHYDE IN DRAIN FLUID _____

17. HEAT DISINFECT MACHINE _____

18. CLEAN EXTERIOR _____

19. ATTACH PROPER CONCENTRATE DILUTION LABELS AND ADAPTERS _____

REPAIRS NEEDED_____

TRAVEL HOURS_____ **LABOR HOURS**_____

RES SIGNATURE_____ **DATE** _____

CUSTOMER SIGNATURE_____ **DATE**_____

PART I - FILE PART II - QUALITY PART III - SERVICE MGR. PART IV - R.E.S. PART V - CUSTOMER

S E C T I O N V I I

TROUBLESHOOTING

DEBUG SCREENS

To enter the Debug Screens, press the up and down keys simultaneously.

SCREEN 0: HYDRAULIC FLOW

Acid =	The number of acid pump steps (per stroke) sent to the actuator board from the functional board. The actuator board will step the acid pump motor this many steps away from the end of stroke sensor. This value is determined by the currently selected concentrate and should make the acid pump deliver APV.
AAcid =	The actual number of acid pump steps sent to the acid pump by the actuator board. The actuator board will step the acid pump motor until the end of stroke is sensed. AACI is the number of steps counted until this end of stroke. If AACI does not equal ACID, an EOS error will be generated.
Bic =	The number of bicarbonate pump steps (per stroke) sent to the actuator board from the functional board. The actuator board will step the acid pump motor this many steps away from the end of stroke sensor. This value is determined by the currently selected concentrate and should make the bicarbonate pump deliver BPV.
ABic =	The actual number of bicarbonate pump steps sent to the bicarbonate pump by the actuator board. The actuator board will step the bicarbonate pump motor until the end of stroke is sensed. ABIC is the number of steps counted until this end of stroke. If ABIC does not equal BIC, an EOS error will be generated.
!AIR =	No Air? Air sensed in air removal chamber 69 = 0. Functional board input pin A7.
Flow Error =	Indicates the presence of a flow error (1 = yes and 0 = no).
Valve Error =	Indicates the presence of a valve error (1 = yes and 0 = no).
Art =	Displays the arterial pressure.
Ven =	Displays the venous pressure.
TMP =	Displays the TMP.
PDial =	Displays the dialysate pressure.
Conductivity cells & temperatures =	Displays the conductivity and temperature at each conductivity cell.
Leak =	Displays the voltage of the blood leak detector.
Dimn =	Displays the voltage of the dimness channel of the blood leak detector.
FLWP =	Chamber full switch A/D value.
DEAP =	Displays the deaeration pump DAC value.
ACFS =	Displays the flow pump DAC value.

SCREEN 1: HYDRAULICS

AMIN = The minimum allowed volume delivered from a calibrated acid pump based upon the current machine settings. This value is used in the preventative maintenance procedure.

AMAX = The maximum allowed volume delivered from a calibrated acid pump based upon the current machine settings. This value is used in the preventative maintenance procedure.

BMIN = The minimum allowed volume delivered from a calibrated bicarbonate pump based upon the current machine settings. This value is used in the preventative maintenance procedure.

BMAX = The maximum allowed volume delivered from a calibrated bicarbonate pump based upon the current machine settings. This value is used in the preventative maintenance procedure.

A160 = Stroke volume of the acid pump at 160 steps per stroke. This volume was determined and put into battery RAM during acid pump calibrations.
(For example: 8620 = 0.8620 ml/stroke).

B160 = Stroke volume of the bicarb pump at 160 steps per stroke. This volume was determined and put into battery RAM during bicarb pump calibrations.
(For example: 8620 = 0.8620 ml/stroke).

A220 = Stroke volume of the acid pump at 220 steps per stroke. This volume was determined and put into battery RAM during acid pump calibrations.
(For example: 8620 = 0.8620 ml/stroke).

B220 = Stroke volume of the bicarb pump at 220 steps per stroke. This volume was determined and put into battery RAM during bicarb pump calibrations.
(For example: 8620 = 0.8620 ml / stroke).

APV = Current acid pump stroke volume based on ACID.
(For example: 8620 = 0.8620 ml / stroke).

BPV = Current bicarb pump stroke volume based on BIC.
(For example: 8620 = 0.8620 ml / stroke).

CTCD = Calculated theoretical conductivity based on Na+, bicarbonate, and concentrate selected.

NaRT = Remaining time in a sodium variation program (SVS). This value will be 0:00 if no program is running.

HI ART = Hardware high arterial alarm (actuator).

AART = Calculated arterial pressure by the actuator board to within 1 mmHg.

LO ART = Hardware low arterial alarm (actuator).

AVEN = Calculated venous pressure by the actuator board to within 1 mmHg.

HI VEN = Hardware high venous alarm (actuator).

ATMP = Calculated TMP by the actuator board to within 1 mmHg.

LO VEN = Hardware low venous alarm (actuator).

SCREEN 1: HYDRAULICS (Cont.)

ART = Functional board precise arterial pressure to within 1 mmHg.

HI TMP = Hardware high TMP alarm (actuator).

VEN = Functional board precise venous pressure to within 1 mmHg.

LO TMP = Hardware low TMP alarm (actuator).

TMP = Functional board precise TMP to within 1 mmHg.

BYERR Bypass valve error (1 = yes : 0 = no). Not used.

NO EOS No EOS (end of stroke) from the acid or bicarb pump. NOTE: Each concentrate pump has two optical sensors. These sensors monitor the EOS or the point where the volume of the diaphragm pump is completely pressed out. The pump steps away from this EOS by the number of steps defined in ACID or BIC. The pump steps toward the EOS until the EOS is sensed. The number of steps that are counted is AACI or ABIC. The number of steps toward the EOS should equal the number of steps away from the EOS i.e. ACID = AACI or BIC = ABIC. If there is a discrepancy between steps sent and steps used an EOS error will be issued by the actuator board. NO EOS means that the AACI or ABIC number is equal or greater than 500. (1 = yes and 0 = no).

BYPASS = Bypass is active. The machine goes into bypass when we get a temperature or conductivity alarm. (1 = yes and 0 = no).

ALWEOS = Always EOS (end of stroke) from the acid or bicarb pump. NOTE: Each concentrate pump has two optical sensors. These sensors monitor the EOS or the point where the volume of the diaphragm pump is completely pressed out. The pump steps away from this EOS by the number of steps defined in ACID or BIC. The pump steps toward the EOS until the EOS is sensed. The number of steps that are counted is AACI or ABIC. The number of steps toward the EOS should equal the number of steps away from the EOS i.e. ACID = AACI or BIC = ABIC. If there is a discrepancy between steps sent and steps used an EOS error will be issued by the actuator board. NO EOS means that the AACI or ABIC number is equal or greater ALWEOS means that the AACI or ABIC number is less than 100 steps. (1 = yes and 2 = no).

FIL ACT = Fill program is active. (1 = yes and 0 = no).

FIL STA = Fill program has started. (1 = yes and 0 = no).

DOUBLE = Bicarb pump double stroke. NOTE: The bicarb pump does not necessarily double stroke as it does in the E and D model machines.

ACT BLD = Blood sensed in the optical detector by the actuator. (motherboard input pin A4 : 1 = yes and 0 = no).

FLW OFF = Flow is off. (motherboard input pin C2 : 1 = yes and 0 = no).

OTMP = Raw TMP value without taking blood or dialysate flow into account.

FLVERR = Flow valve error (1 = yes : 0 = no). Not used.

BFLW = Current Blood Flow Rate in ml/min.

SCREEN 1: HYDRAULICS (Cont.)

FLWP = 255 minus this value = DAC value sent to flow pump from the actuator board.

PHT ACT = On-line pressure holding test is active. (1 = yes and 0 = no).

DEAP = 255 minus this value = DAC value sent to deaeration pump from the actuator board.

NPHT = Seconds until next on-line pressure holding test.

TEMP = Calculated temperature (example 370 = 37.0°C).

PHT0 = Result of PHT first valve combination.

5V EST. = Estimated 5V from the power supply.

PHT1 = Results of PHT second valve combination.

12V EST. = Estimated 12V from the power supply

BPCE = Blood pump communication errors. This is a number of how many errors have occurred.

SALV = Saline volume. Not used.

VERR = Valve error (1 = yes : 0 = no). Not used.

SCREEN 2: INPUTS / OUTPUTS

UFPULS = UF pulse? This pin monitors the UF pump. It goes from 0 to 1 as the UF pump strokes. Also, if the UF pump solenoid goes to a high resistance state this pin goes high (1) constantly causing the functional board to issue a UF PUMP ALARM. Functional board input pin A29.

LINOFF = Lines off? This pin = 1 if both the red and the blue dialysate connectors are out of the shunt. Both dialysate lines must be in the shunt (LINOFF = 0) to start the cleaning modes. Functional board input pin A30.

!EMPTY = No empty? This pin = 0 if the red dialysate line is out of the shunt and the blue connector is in the shunt. This configuration enables the "emptying program" causing all spent side of the balancing chamber to close while the flow pump runs. This "empties" the dialyzer of dialysate. Functional board input pin A31.

FLWOUT = This pin is directly from balancing chamber valve 33 and toggles from 1 to 0 as the balancing chamber valves cycle. 1 = valve 33 open. Functional board input pin C1.

SERVSW = Service switch? In non-service mode = 0.

BICOUT = Bicarb connector out? Bicarb connector not plugged into machine = 1 (reed switch K12 in the "open" state). Functional board input pin A3.

!AIR = No air? Air sensed in air removal chamber 69 = 0. Functional board input pin A7.

!BLOOD = No Blood? Blood sensed in the optical detector = 0. Functional board input pin C23.

CVRCLS = Shunt door closed? Shunt door closed = 1. Functional board input pin C6.

DIAVLO = Dialyze valve 24 open? Valve 24 open = 1 i.e. machine is not in bypass. This pin must = 0 if a bypass alarm becomes present. Functional board input pin C7.

FLWSTP = Flow stopped? This pin = 1 when flow stops for any reason. All balancing chamber valves are off during flow stop. Functional board input pin C2. =90-

ACIOUT = Acid connector out? Acid connector not plugged into machine = 1 (reed switch K11 in the "open" state). Functional board input pin A21.

LD UP = Level detector switch up? Venous chamber level adjust switch held up = 1. The level adjust switch is used to raise the level in the venous drip chamber. Pin C4 on the motherboard connector P1.

LD DWN = This pin is always = 0 (unused). Pin C5 on the motherboard connector P1.

SWPNL = This pin is always = 1. Pin A8 on the motherboard connector P1.

!SWITCH = Power button not pushed? Pushed = 0. Pin A9 on the motherboard connector P1.

TRIAC = If the triac is this pin = 0. In the first 10 seconds, after entering dialysis mode, the heater relay (RL 3) is turned off so that no voltage is available to the triac while the temperature control circuit, on the sensor board, is fully on. This pin should be = 1 since there is no voltage available to the triac. If the pin goes low (TRIAC = 0) during this time a "HEATER RELAY TEST FAIL" will be issued by the functional board. Pin A10 on the motherboard connector P1.

!EXTAL = Unused

SCREEN 2: INPUTS / OUTPUTS (Cont.)

!HEPAL = No heparin pump alarm? No alarm = 1. Pin C25 on the motherboard connector P1.

!SNGNE = Single needle (venous) blood pump not running? Venous blood pump running = 0. During single needle operation, when the arterial blood pump runs, the venous blood pump does not and vise versa. This pin monitors the blood pump during so that the functional board can control the venous clamp. When the arterial blood pump runs, in single needle operation, the venous clamp is closed. Pin C26 on the motherboard connector P1.

!BPSTP = No blood pump(s) stopped alarm? Blood pump (arterial or venous) stopped alarm = 0 (low). If the blood pump(s) are turned on this pin will = 0 15 or 30 seconds after the blood pump(s) stopped stop for any reason. Pin C27 on the motherboard connectorP1.

VENBP = Operational venous (single needle) blood pump present? Pump present = 1. This pin must = 1 in order to turn single needle function on. Pin C28 on the motherboard connector P1.

!LD AL = No level detector alarm? No level detector alarm = 1. Pin C24 on the motherboard connector P1.

V12 OK = +12 Vdc ok? This power logic board constantly monitors the +12V power supply and inform the functional board of its state via this pin (motherboard P2 connector, pin A21). 12 +/-0.3 Vdc = OK. If the voltage is outside this range the functional board will issue a 12 volt high or low alarm

VNTVLO = Vent valve open? Open vent valve in self prime = 1. The vent valve is located inside the level detector module and vents the venous drip chamber to atmosphere when open. This pin does not go high when manually raising the venous level. Pin C15 on the motherboard connector P1.

CLAMPO = Venous bloodline clamp open? Open clamp = 1. Pin C16 on the motherboard connector P1.

CLR AL = Clear alarms? Reset alarms to modules = 1. NOTE: This occurs to quickly to be seen in DEBUG. Pin C17 on the motherboard connector P1.

!BPSTP = No blood pump stopped? Stop blood pump(s) = 0. Pin C18 on the motherboard connector P1.

BPSPEC = Blood pump special? Special blood pump control = 1. This pin inputs the blood pump module and controls the blood pump to a maximum speed of 150 ml/min. This occurs whenever the venous level switch is held up to raise the venous drip chamber level. Pin C19 on the motherboard connector P1.

RINSE = In rinse? In rinse program = 1. Pin A22 on the motherboard connector P1.

!FLOW = No flow? Flow off = 1 with no water alarm. Pin A23 on the motherboard connector P1.

!RELPR = No release pressure? Release dialysate pressure = 0. This occurs when resetting a TMP alarm. This pin in not connected. Pin A24 on the motherboard connector P1.

!DIAAL = No dialysate alarms? Dialysate alarms = conductivity or temperature alarm or shunt door open = machine in bypass = 0 i.e. valve 24 closed, valve 26 open. NOTE: This pin is not connected. Pin A25 on the motherboard connector P1.

SCREEN 2: INPUTS / OUTPUTS (Cont.)

!FILL = No fill? Not in fill program = 1. NOTE: This pin is not connected. Pin A26 on the motherboard connector P1.

SNG NE = Single needle? Turn single needle on = 1. Pin C20 on the motherboard connector P1.

!CNDRE = No conductivity resistor? Normally = 1. During conductivity cell calibrations the functional board takes this pin low (! CNDRE= 0) and turns on the sensor board relay (RL2). This puts a fixed resistor (R6) into the sensor board conductivity counter circuit. Pin A6 on the motherboard connector P1.

!CNDCA = No conductivity calibration? Normally = 1. During conductivity cell calibrations the functional board takes this pin low (!CNDCA = 0) and turns on the sensor board relay (RL1). This removes the conductivity cell from the conductivity counting circuit. Pin A5 on the motherboard connector P1.

HEAT = Heat relay on? On = 1. The heater relay RL3), located in the upper power supply on the power control board, supplies 120 Vac to the triac. The functional board keeps RL3 on as long as temperature remains below 41.5ºC in dialyze mode or 90ºC in heat disinfect. Pin A 15 on the motherboard connector P1.

TRIWDR = Triac watchdog reset? Normally = 0. During power up the functional board tests the heater relay (RL 3), located in the upper power supply on the power control board, for proper function. Reset = 1. Pin A18 on the motherboard connector P1.

!DISHE = No heat disinfect? Machine in heat disinfect = 0. Generates high temperature for heat disinfect. Pin C14 on the motherboard connector P1.

WARNSO = Warning sound on? Sound on = 1. Pin A14 on the motherboard connector P1.

ALM SO = Alarm sound on? Sound on = 1. Pin A13 on the motherboard connector P1.

NURSEC = Nurse call on? ON = 1. Pin A16 on the motherboard connector P1.

TRI_GRE = Green traffic light on? Green traffic light on = 1. Traffic lights are optional and hang on the IV pole. Since they hang on the IV pole they can be seen from across the unit.

TRI_YEL = Yellow traffic light on? Yellow traffic light on = 1.

TRI_RED = Red traffic light on? Red traffic light on = 1.

SCREEN 3: ACTUATOR

These 12 values may mean anything and will vary between different versions of actuator board software. They are used for arbitrary debugging.

ACT0	ACT1	ACT2
ACT3	ACT4	ACT5
ACT6	ACT7	ACT8
ACT9	ACT10	ACT11

SCREEN 4: ELECTRONICS

LEAK = Blood leak receiver (in Vdc). Sensor cable connector 2 pin 6. Sensor board ADC input channel 0.

DIMN = Blood leak dimness receiver (in Vdc). Sensor cable connector 2 pin 7. Sensor board ADC input channel 1.

PDIA = Dialysate pressure (in Vdc). Sensor cable connector 2 pin 8 and 10. Sensor board ADC input channel 4.

TEMP = Temperature monitor NTC3 (in Vdc). Sensor cable connector 2 pin 12. Sensor board ADC input channel 5.

ABPR = Arterial blood pump rate (in Vdc). Sensor board input pin A28. Sensor board ADC input channel 6.

PART = Arterial pressure (in Vdc). Sensor board input pin A27. Sensor board ADC input channel 2.

5V = 5V power supply (in Vdc). Sensor board input pin C31. Sensor board ADC input channel 8.

PVEN = Venous pressure (in Vdc). Sensor board input pin A32. Sensor board ADC input channel 3.

24V = 24V power supply (in Vdc). Sensor board input pin C30. Sensor board ADC input channel 9.

ASET = Arterial blood pump set (in Vdc). Sensor board input pin A12. Sensor board ADC input channel 10.

VSET = Venous (single needle) blood pump set (in Vdc). Sensor board input pin A11. Sensor board ADC input channel 11.

VBPR = Venous (single needle) blood pump rate (in vdc). Sensor board input pin A29. Sensor board ADC input channel 7.

XTRM = Last byte received from Transterm (actuator board).

CMS = Undefined.

The following signals are Self-Test signals:

RAWT	MODE#	GOTT
DOING	TSTT	TIME
CURT	DELAY	FAIL#

The following are functional board communication data used in software development:

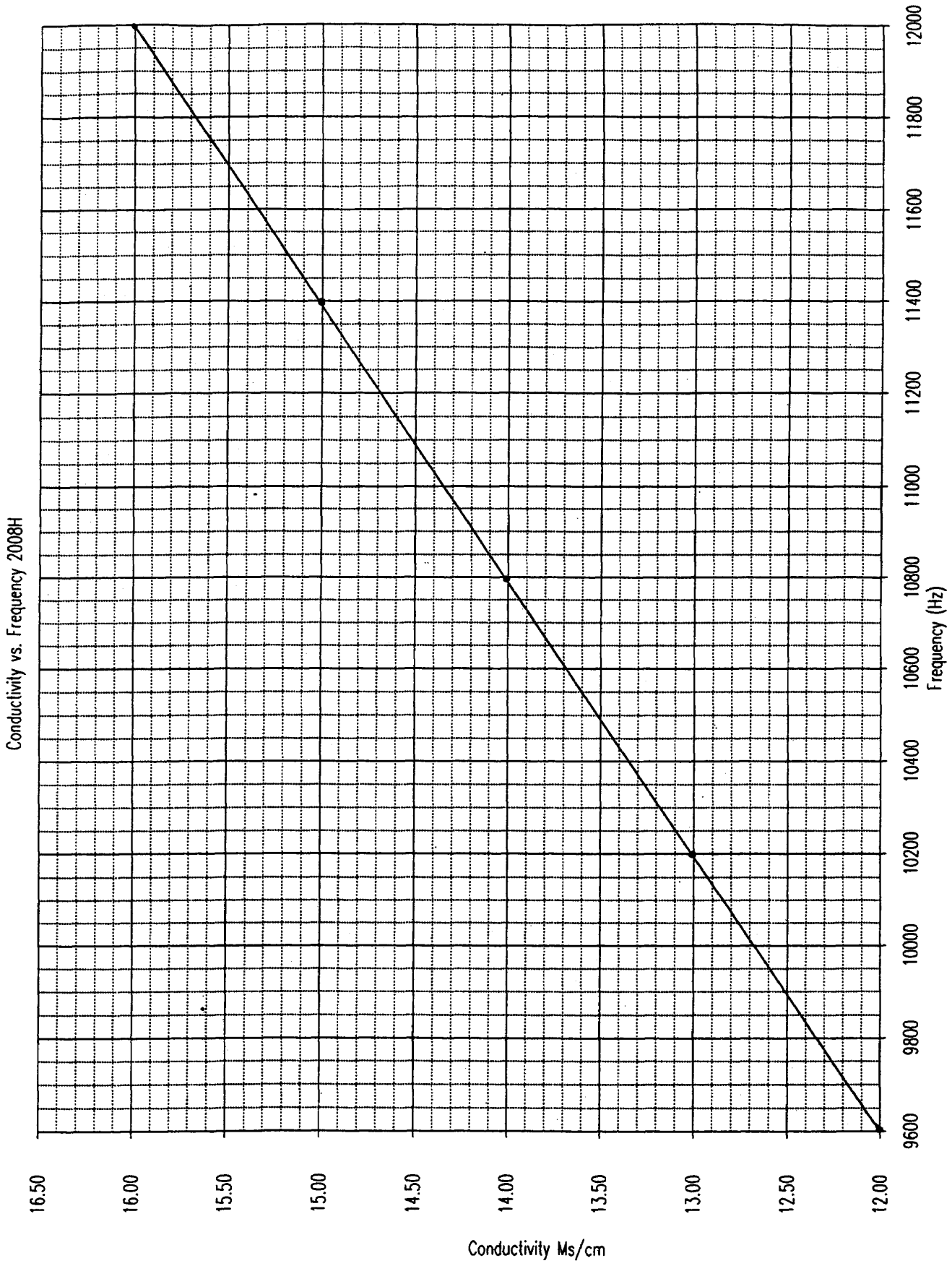
XTMI	FDS#	XTMD
FDSX	BPMI	FDSR
BPMO	00F2	FDSI
00F4	FDSO	00F6

SCREEN 5: ON-LINE CLEARANCE

ACOND =	Conductivity derived through the actuator board.
AFREQ =	The frequency measured by the actuator board which corresponds to non-temperature compensated conductivity.
BCV =	Actual balancing chamber volume as per tow strokes (example 609 = 60.9 mL).
!ECH =	Number of times no echo signal was received. This is a communication signal between actuator board and functional board.
!ACK =	Number of times no acknowledge signal was received. this is a communication signal between actuator board and functional board.
!SUM =	Number of bad check sums. This is a communication signal between actuator board and functional board.
I>50 =	The number of times the 50mS interrupt was exceeded.
CELL =	Slope criteria for conductivity calculation (condo = slope *frequency + offset : example 2026 = 2.026).
CREF =	Frequency measurement of the reference resistor done during conductivity calibration.
COFS =	Offset value used in the calculation of conductivity (condo = slope * frequency + offset : example 2394 = 2.394).
OTST =	Results from 0 on-line clearance test. Less than 25 is needed for the test to pass.
TPRE =	Temperature pre-dialyzer (example 3847 = 38.47ºC).
TPOS =	Temperature post-dialyzer (example 3847 = 38.47º)
CPRE =	Conductivity pre-dialyzer (example 14184 = 14.184mS).
CPOS =	Conductivity post-dialyzer (example 14184 = 14.184mS).
CPRE STABLE AT =	Conductivity value of pre-dialyzer sensor when it stabilizes (example 15800 = 15.800mS). This is the pre-conductivity value used in calculating KEU.
CPOS STABLE AT =	Conductivity value of post-dialyzer sensor when it stabilizes (example 15466 = 15.466mS). This is the post-conductivity value used in calculating KEU.
FPRE =	Frequency pre-dialyzer. This value is used in calculating pre-dialyzer conductivity. NOTE: Frequency is read as cycles per second, but this value is read as cycles per 2 seconds or twice the frequency (example 11290 = 5645 hertz).
FPOS =	Offset Frequency post-dialyzer. This value is used in calculating post-dialyzer conductivity, but is offset so it does not interfere with the CPRE frequency. NOTE: Frequency is read as cycles per second, but this value is read as cycles per 2 seconds or twice the frequency (example 14290 = 7145 hertz).

SCREEN 5: ON-LINE CLEARANCE (Cont.)

QD =	Actual dialysate flow during on-line clearance. Taken when pre and post conductivity is at upper and lower point of conductivity.
QB =	Actual blood flow during on-line clearance. Taken when pre and post conductivity is at upper and lower point of conductivity.
QD1 =	Actual dialysate flow currently.
QBS =	Blood flow stability. Must be below 20 to run on-line clearance (0 is stable).
QDS =	Is dialysate flow stable? (1 = yes : 0 = no).
QF =	Actual UF rate during on-line clearance. Taken when pre and post conductivity is at upper and lower point of conductivity.
KEU1 =	First clearance value taken.
KEU2 =	Second clearance value taken.
KEU3 =	Third clearance value taken.
KEU4 =	Fourth clearance value taken.
KEU5 =	Fifth clearance value taken.
KEU6 =	Sixth clearance value taken (latest).
MEAN KEU =	The time waited average of the last 6 clearance (KEU) values.
PRE DEV VAL =	How much the pre-conductivity has deviated from the previous value. The closer to 0 the least amount of deviation.
PRE STBL CT =	How stable the pre conductivity value is. The closer to 0 the least amount of deviation.
POST DEV VAL =	How much the post-conductivity has deviated from the previous value. The closer to 0 the least amount of deviation.
POST STBL CT =	How stable the post conductivity value is. The closer to 0 the least amount of deviation.
OLC STATUS =	The status of on-line clearance (1 = top point of conductivity : 2 = bottom point of conductivity : 0 = not running).


Conductivity vs. Frequency 2008H
Frequency (Hz)
12000
11800
11600
11400
11200
11000
10800
10600
10400
10200
10000
9800
9600
16.50
16.00
15.50
15.00
14.50
14.00
13.50
13.00
12.50
12.00
Conductivity Ms/cm

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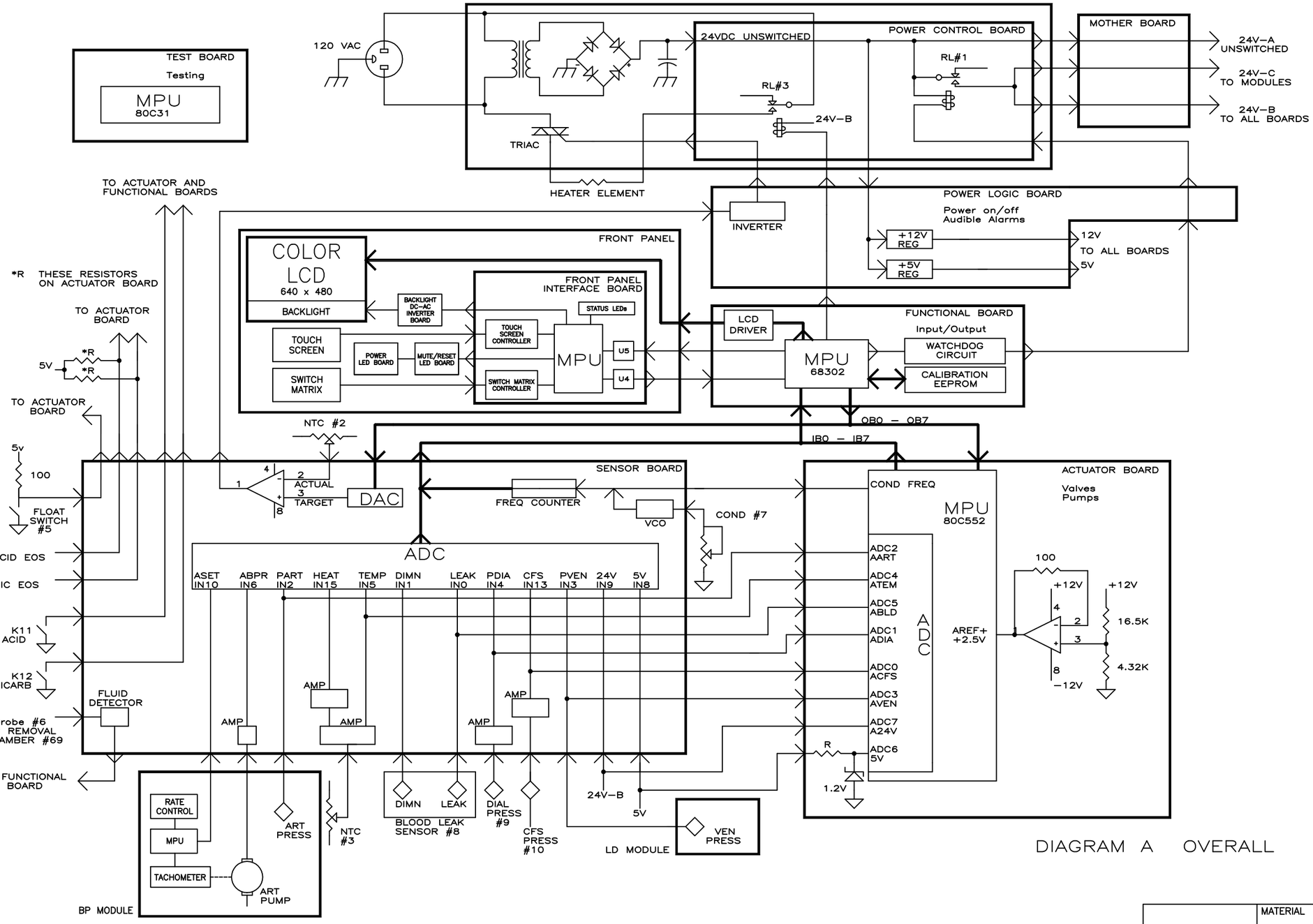

DIAGRAM A OVERALL

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1 OF 11

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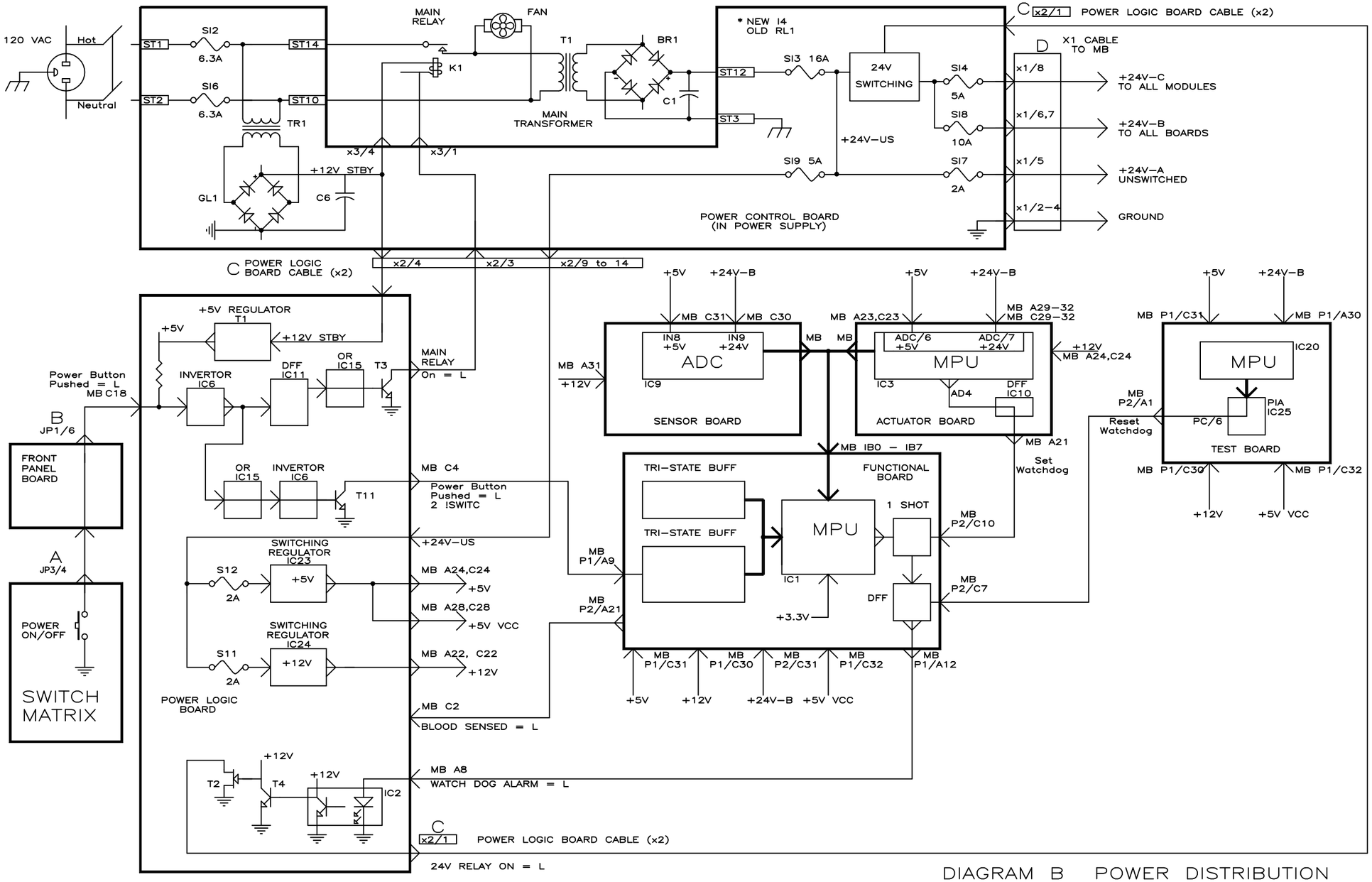

DIAGRAM B POWER DISTRIBUTION

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290174

REV. A

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SHEET 2 OF 11

REV	ECO #	BY	DATE	CHK	REVISION
A	7193	BH	6.15.00	JEF	RELEASE

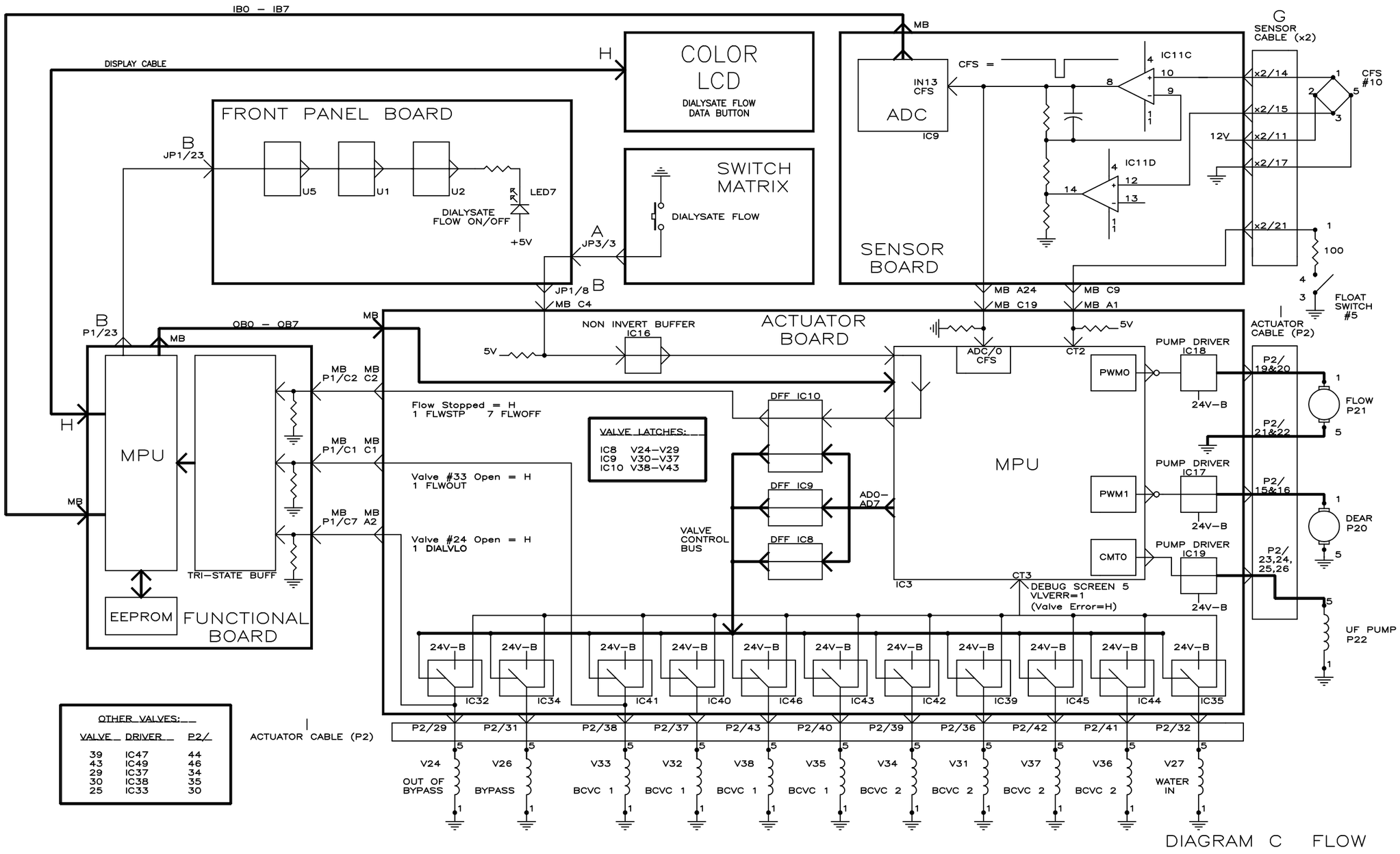

DIAGRAM C FLOW

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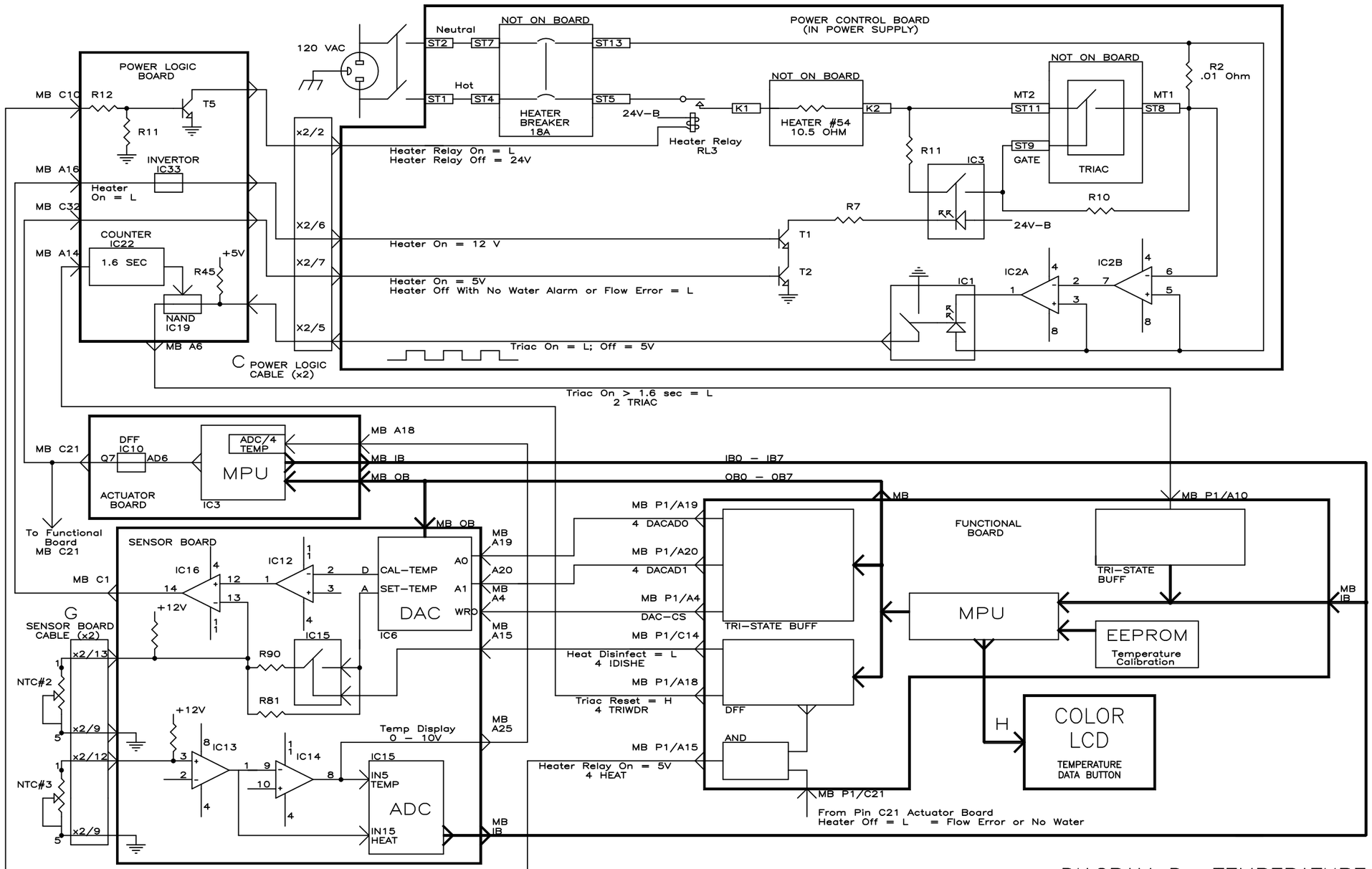

DIAGRAM D TEMPERATURE

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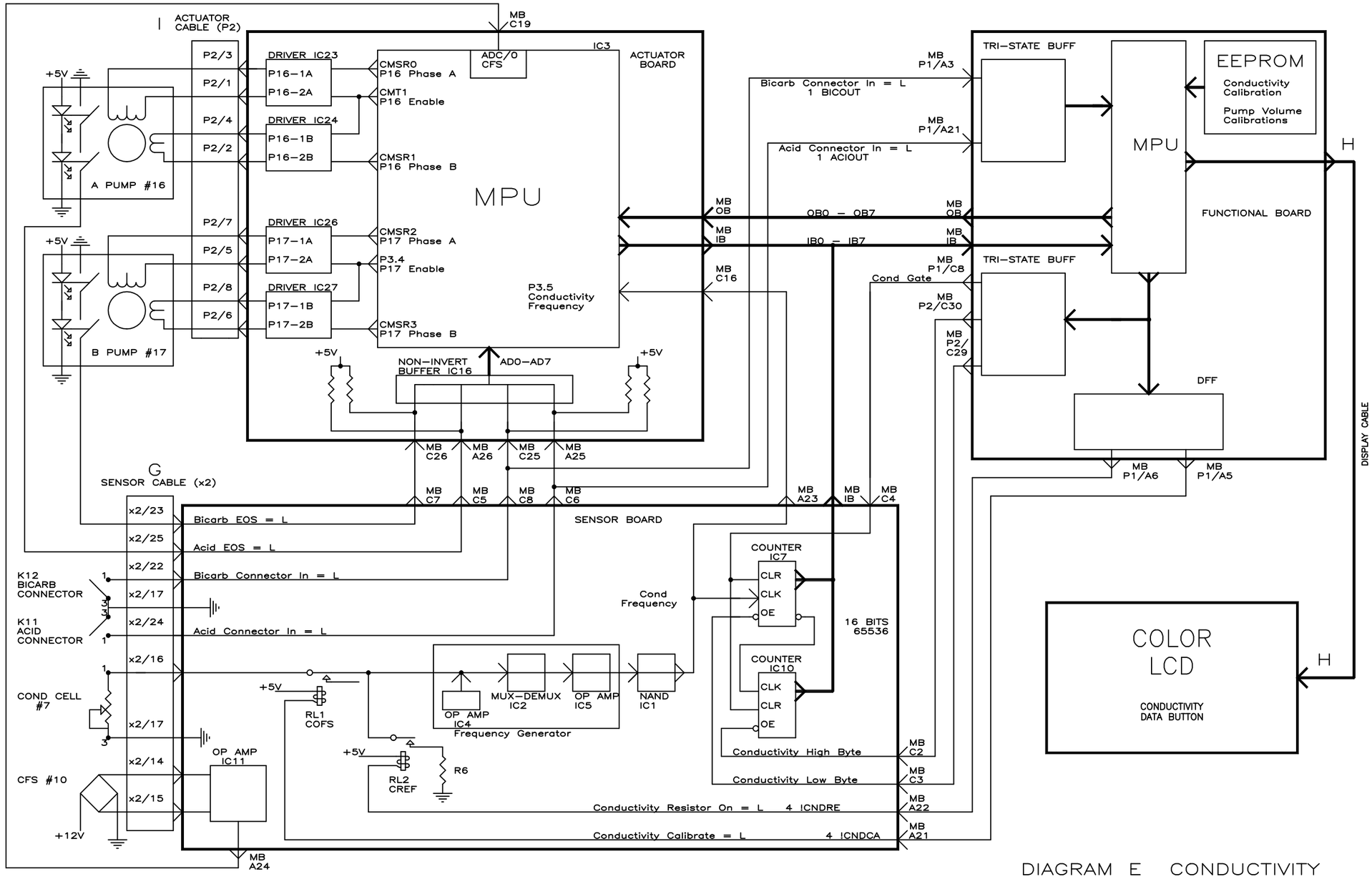

DIAGRAM E CONDUCTIVITY

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SHEET 5 OF 11

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DIALYSATE IN
BLOOD LEAK SENSOR #8
DIMNESS
BLOOD LEAK
DIALYSATE OUT
Dialysate Press #9
G
SENSOR CABLE (x2)
SENSOR BOARD
IC9
ADC
X2/17
x2/8
x2/10
x2/11
x2/7
x2/6
OP AMP IC11
OP AMP IC5
T1
+12V
IN4 P-DIAL
IN1 DIMN
IN0 BL
IN3 P-VEN
IN2 P-ART
IN10 ART SET
IN6 ART BPR
IN5 TEMP
IN15 HEAT
OP AMP IC14B
OP AMP IC13
OP AMP IC14
COUNTERS IC7 & 10
x2/12
x2/16
NTC#3
COND CELL #7
LEVEL DETECTOR MODULE
Venous Press Transducer
Venous Line Clamp
Optical Detector
Level Switch
Vent Valve
HH Level Detector Alarm = L (Air In Blood)
GG Close Venous Line Clamp = L
FF Blood Sensed = L (Patient Present)
EE Open Vent Valve = H
DD Level Switch Held Up = H
LD/14
LD/4
LD/8
LD/3
LD/5
LD/1
MB A32
MB A27
MB A12
MB A28
ARTERIAL BLOOD PUMP MODULE
Arterial Press Transducer
Rate Control
MPU
Tach-ometer
Blood Pump
CC Special Control = H (With Level Switch Held Up)
BB Stop Blood Pump = L
AA Blood Pump Stopped = L (After 15 or 30 Sec Delay)
BP/3
BP/1
BP/8
BP/7
BP/14
BP/10
MB IB
ACTUATOR BOARD
7 ACTBLD
FF
MB A4
DRIVER
DRIVER
DRIVER
UF PUMP #22
V26
V24
MB IB
MB OB
MB C20
MB A2
UF Pump Stroke = H
V24 Open = H
MB IB
MB OB
MB P1/A29
MB P1/C7
1 UFPULS
1 DIALVLO
FUNCTIONAL BOARD
AA MB P1/C27 2 !BPSTP
BB MB P1/C18 3 !BPSTP
CC MB P1/C19 3 BPSPEC
DD MB P1/C4 2 LD UP
EE MB P1/C15 3 VNTVLO
FF MB P1/C23 1 !BLOOD
GG MB P1/C16 3 CLAMPO
HH MB P1/C24 2 !LD AL
MB P1/C25 2 !HEPAL
Heparin Alarm = L
4 WARNSO 4 ALM SO
MB P1/A14
MB P1/A13
MB P1/A12
MB P2/A21
Warning Sound On=H
Alarm Sound On=H
Watch Dog=L
Blood Sensed=L
HEPARIN MODULE
L
HEP/4
MB A10
MB C8
MB A8
MB C2
P4/3
P4/4
ALARM SPEAKER
POWER LOGIC BOARD
T2
MB A12
B
H
COLOR LCD
ARTERIAL PRESSURE
VENOUS PRESSURE
TRANSMEMBRANE PRESSURE
CONDUCTIVITY
TEMPERATURE
+24V-B
+24V-C
MAIN TRANSFORMER
+24V
RL1
POWER CONTROL BOARD
POWER SUPPLY
FRONT PANEL BOARD
U1
MPU
U2
U3
SVS
FLOW
PRIME
OVERRIDE
STAT/DEFLATE
HEPARIN
UF
BLOOD LEAK
AIR DETECTOR
BYPASS
MINOR
+5V
N
N
MUTE/RESET LED BOARD
RESET
MUTE
O
POWER LED BOARD
POWER

DIAGRAM F MONITORS AND ALARMS

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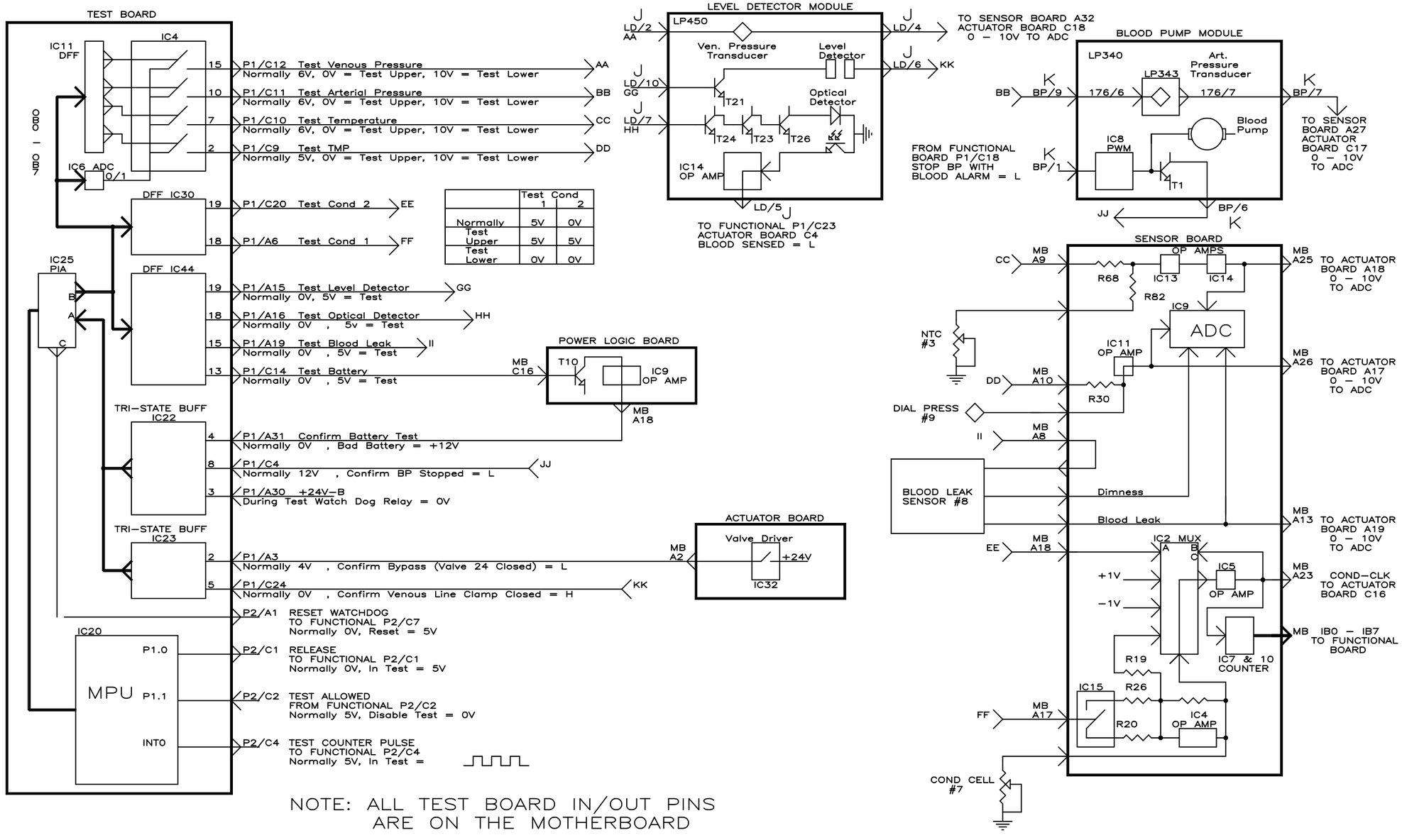

NOTE: ALL TEST BOARD IN/OUT PINS ARE ON THE MOTHERBOARD

DIAGRAM G TESTING

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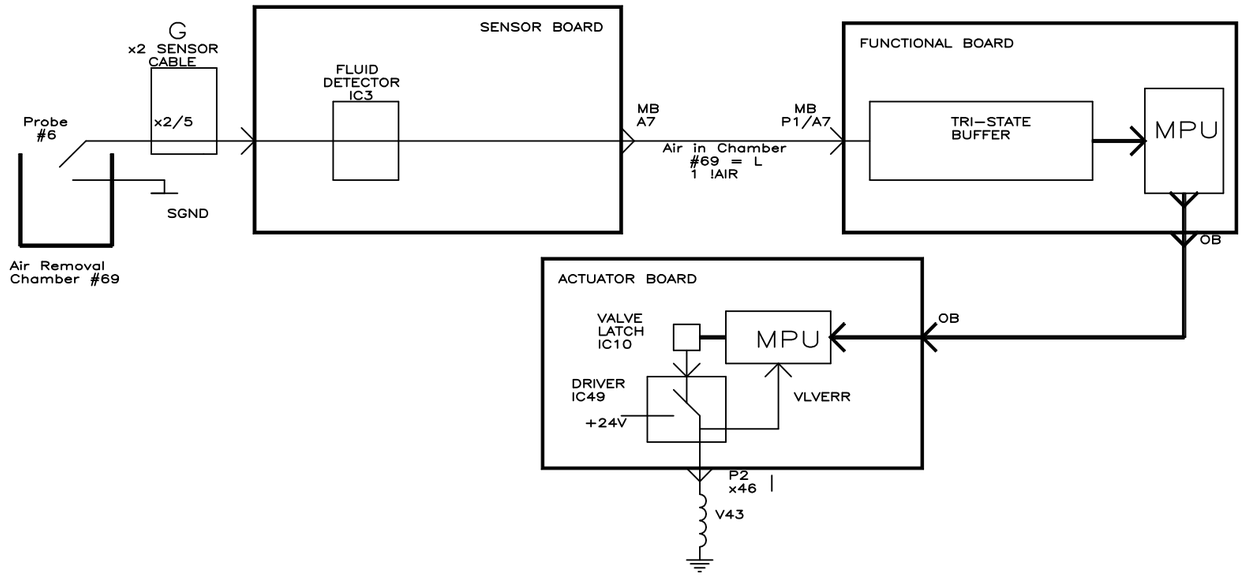

DIAGRAM H FILL PROGRAM

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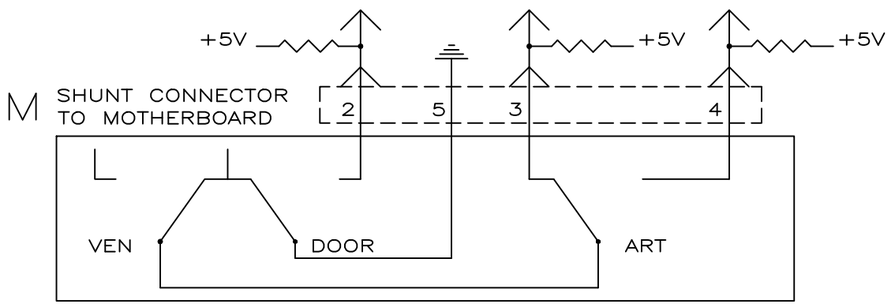
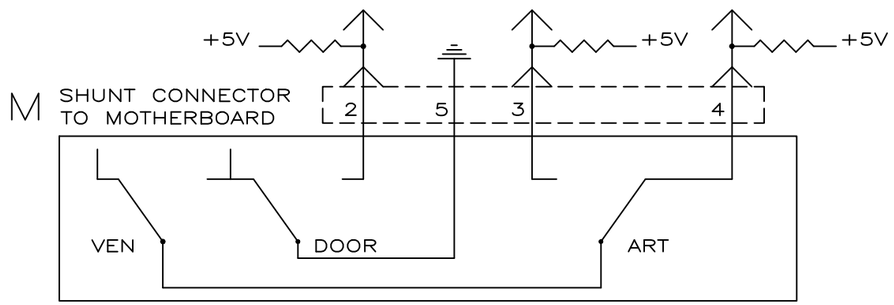
REV	ECO #	BY	DATE	CHK	REVISION
A	7193	BH	6.15.00	JEF	RELEASE

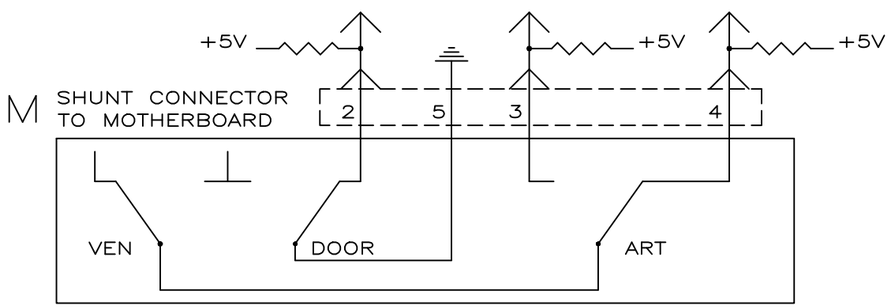
CONNECTOR P8 TO MOTHERBOARD
Pin 1 = Not Connected
Pin 2 = To functional board P1/C6, actuator board C6
Pin 3 = To functional board P1/A30, actuator board A5
Pin 4 = To functional board P1/A31, actuator board C5
Pin 5 = Ground



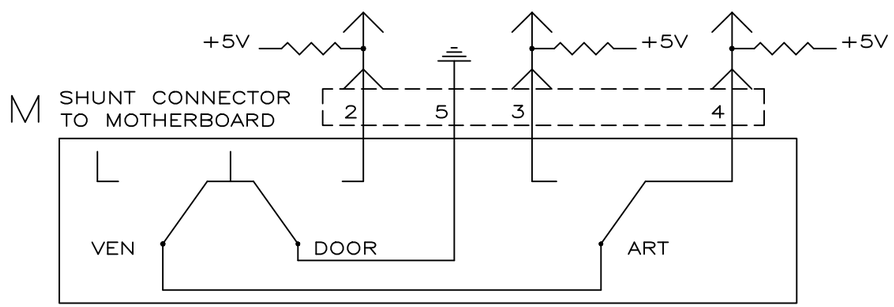
Both lines in shunt; shunt door closed
Pin 2 = +5V (Door closed)
Pin 3 = 0V (Both lines in shunt)
Pin 4 = +5V (Emptying not active)



Neither line in shunt; shunt door closed
Pin 2 = +5V (Door closed)
Pin 3 = +5V (Both dialysate lines not in)
Pin 4 = +5V (Emptying not active)



Shunt door open
Pin 2 = 0V (Door open)
Pin 3 = +5V (Both dialysate lines not in)
Pin 4 = +5V (Emptying not active)



Venous line in shunt, arterial line not in, shunt door closed
Pin 2 = +5V (Door closed)
Pin 3 = +5V (Venous line in, arterial line not in)
Pin 4 = 0V (Emptying activated)

DIAGRAM I SHUNT DOOR SWITCH CONFIGURATIONS

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	DATE	NAME
DRAWN	3.25.99	B. LEPARD

MATERIAL

2008K ELECTRONIC BLOCK DIAGRAM

SCALE NONE

FRESENIUS

290174

REV. A SHEET 9 OF 11

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REV	ECO #	BY	DATE	CHK	REVISION
A	7193	BH	6.15.00	JEF	RELEASE

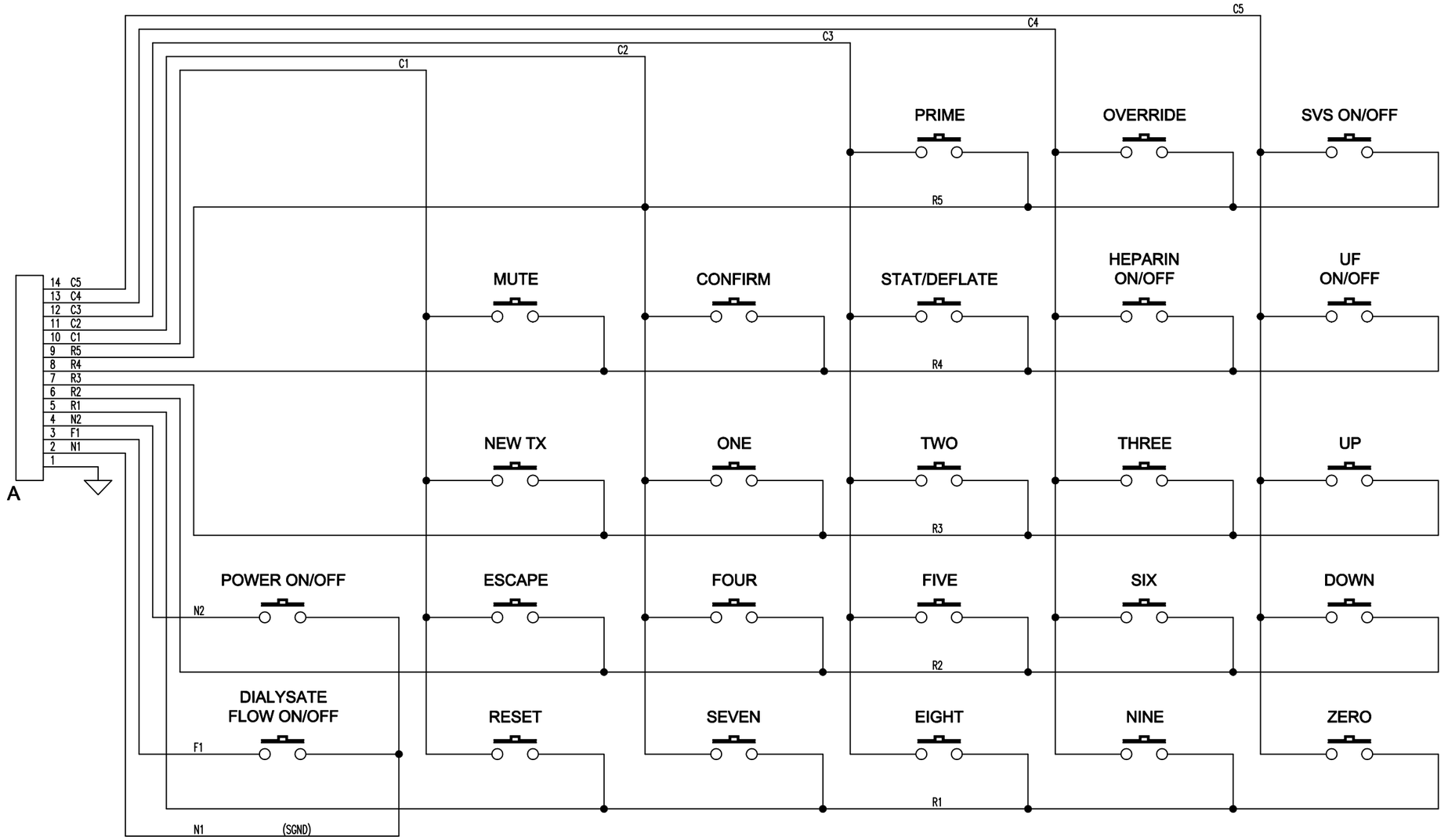

DIAGRAM J FRONT PANEL SWITCH MATRIX

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2008K ELECTRONIC BLOCK DIAGRAM

SCALE NONE

FRESENIUS

290174

REV. A

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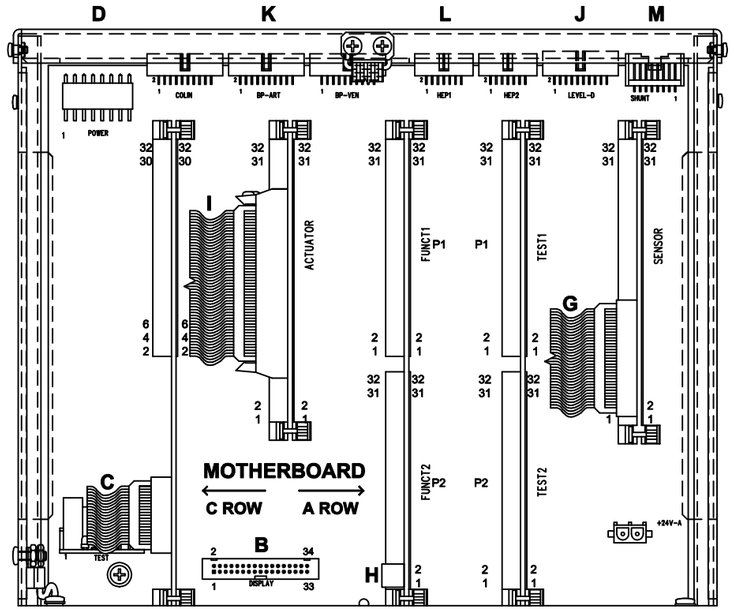
REV	ECO #	BY	DATE	CHK	REVISION
A	7193	BH	6.15.00		RELEASE

CARD CAGE
LEFT TO RIGHT:
POWER LOGIC BOARD
ACTUATOR BOARD
FUNCTIONAL BOARD
TEST BOARD
SENSOR BOARD



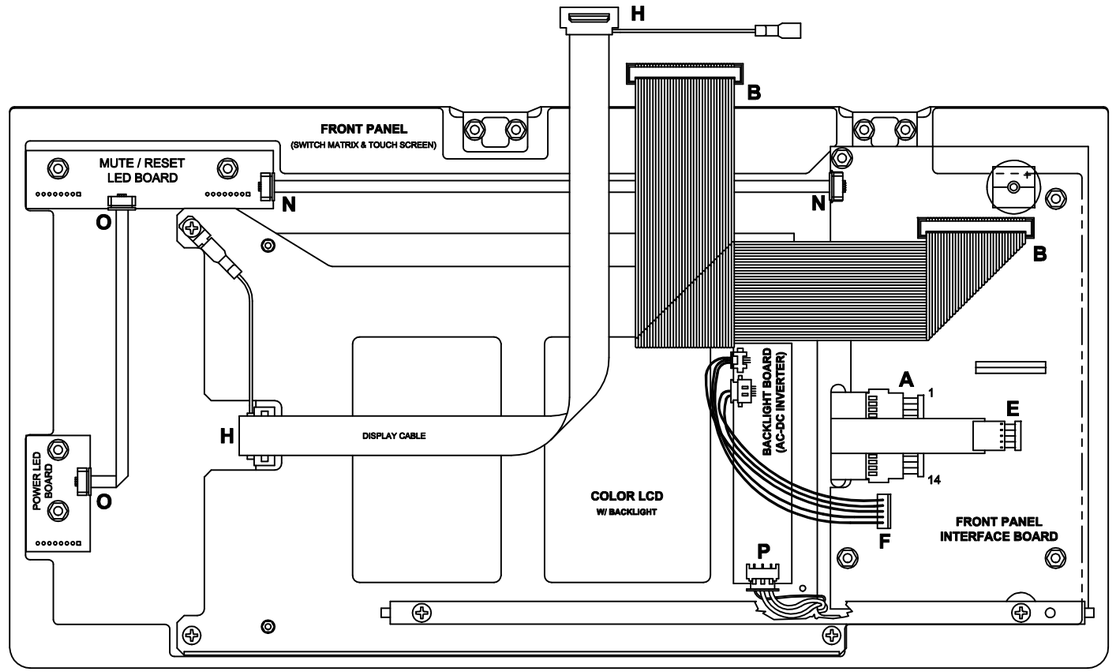


DIAGRAM K CARD CAGE AND DISPLAY BOARD

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	DATE	NAME
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MATERIAL

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2008K ELECTRONIC BLOCK DIAGRAM

SCALE NONE

290174

REV. A
SHEET 11 OF 11

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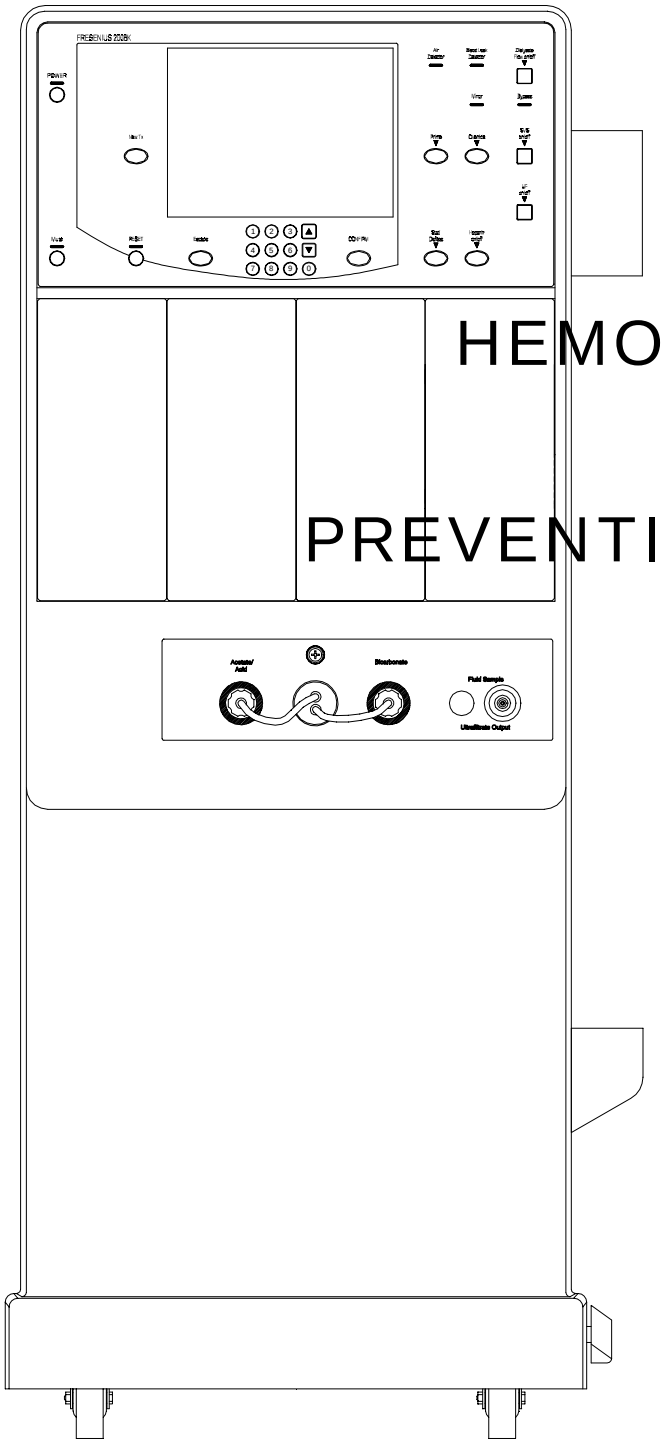
S E C T I O N V I I I

MAINTENANCE



FRESENIUS 2008K HEMODIALYSIS SYSTEM

PREVENTIVE MAINTENANCE PROCEDURES

Part Number 507297 Rev. A

FRESENIUS USA, INC.

2637 Shadelands Drive, Walnut Creek, CA 94598

800-227-2572 or 925-295-0200

REGIONAL EQUIPMENT SPECIALIST: _____

FRESENIUS 2008K HEMODIALYSIS SYSTEM

PREVENTIVE MAINTENANCE PROCEDURES

Part Number 507297 Rev. A

INCLUDING
PREVENTIVE MAINTENANCE CHECKLISTS
QUARTERLY/1000 HOUR AND ANNUAL/4000 HOUR

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WARNINGS

Shock hazard. Refer servicing to qualified personnel.

Failure to install, operate and maintain this equipment according to the manufacturer's instructions may cause patient or operator injury or death.

Never perform maintenance when a patient is connected to the machine. If possible, remove the machine from the treatment area when it is being serviced. Label the machine to ensure it is not accidentally returned to clinical use before the service work is completed. Always fully test the machine when maintenance is completed. Confirm dialysate conductivity and pH level before returning the machine to clinical use.

PREVENTIVE MAINTENANCE PROCEDURES
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NOTE

This document is written for Fresenius 2008K Hemodialysis Systems using software versions 1.12 or later.

1.0 INTRODUCTION

Preventive Maintenance for the Fresenius 2008K Hemodialysis System is simple and straightforward. Maintenance is performed in only two intervals: Quarterly or after 1000 hours of operation, and annually or after 4000 hours of operation. The maintenance procedures have been devised to require a minimum of time while ensuring that the machine is maintained in optimum operating condition.

Included in the Preventive Maintenance procedures are tests to verify normal machine operation. Should the machine fail to pass any of these tests, repair or re-calibrate as needed, then repeat the tests until the specifications are met before returning the machine to service.

Checklists are provided in the back of this manual to record the work done. Make copies of these checklists as needed. Your initials on the checklist certifies that each procedure has been completed and that the machine is performing according to the specifications given.

1.1 TEST EQUIPMENT AND SUPPLIES NEEDED

A number of small parts must be available to perform the Preventive Maintenance. Fresenius part number 190098 is a kit of the parts needed, except for the 9-Volt battery that must be replaced during the annual preventive maintenance. An NEDA 1604AC heavy-duty (alkaline type) battery is required. In addition, the following test equipment is needed:

Warning! All of the test equipment used must be maintained and calibrated regularly in accordance with NIST standards. In particular, the conductivity meter must meet the specifications given below. Failure to do so could result in injury or death to the patient or to the operator.

Warning! Disinfect the machine internally and externally and check all pressure transducer protectors for contamination before working on the machine.

- Fresenius Test Kit (part number 150034), which contains two gauges with fittings and hoses for measuring loading pressure and deaeration pressure.
- Dialysate meter to measure dialysate pressure, temperature and conductivity at the ends of the dialysate lines. The meter must be capable of making pressure measurements from -250 mmHg to +400 mmHg with an accuracy of at least ±2 mmHg up to ±200 mmHg and an accuracy of at least 1% and ±1 mmHg beyond ±200 mmHg. The temperature function of this meter must be accurate within 0.2°C from 20°C to 45°C and must be capable of measuring dialysate temperatures up to 85°C with an accuracy of at least ±4.0°C. The conductivity function of this meter must be accurate to within 0.1 mS over a range of 12 mS to 17 mS at a temperature of 25°C.
- Stopwatch with a resolution to 0.01 second and an accuracy of 0.01% or better.
- Fresenius Buret, 25 ml capacity with 0.1 ml graduations (Fresenius part number 290104).
- Graduated cylinder: 1000 ml capacity with a tolerance of 5.0 ml at 1000 ml or better.
- Syringe, 60 cc capacity. Tolerance is not important; the syringe is not used for volume measurements.
- Tubing, 24” long (Fresenius part number 545325).
- Resistor Plug Set for OLC Testing (Fresenius part number 190168).

The following equipment is also required to test the blood pressure module:

- Test Device (Fresenius part number 370090). The Test Device contains two air chambers with calibrated volumes.
- Mercury manometer or equivalent pressure meter accurate to within 1 mmHg at pressures up to 330 mmHg.

1.2 FRONT PANEL CONTROLS

The front panel consists of two areas, the touch screen and the control panel. The touch screen is the area under the glass in the center of the front panel. The control panel surrounds the touch screen and it contains the membrane keys.

Control Panel Operation

Throughout the preventive maintenance procedures, whenever a control panel key is to be pressed, the appropriate key name is surrounded by square brackets as in the following example:

Press the [CONFIRM] key and the screen will change.

In this example, the [CONFIRM] key on the control panel should be pressed.

Touch Screen Operation

The touch screen is designed to display information and is used to enter data. To select a button during a procedure, locate the button on the screen and touch it. Depending on the type of button, the screen will change. Data boxes are also displayed on the touch screen. The following describes the type of buttons and data boxes that will be encountered during the preventive maintenance process.

Data Button

A yellow data button is used to enter a measured volume or value. When the yellow area of the data button is touched, it will change to a darker yellow. The data can be changed using the [▲] or [▼] keys or the value can be entered using the number keys both on the control panel. Once the data is entered, press the [CONFIRM] key and the data button changes back to light yellow. The [Escape] key can be pressed when the data button is dark yellow to abort the data entry and return it to light yellow. The entered data does not get stored until the [CONFIRM] key is pressed.

Some data buttons will change the screen and the data entry will be performed on the new screen.

A gray data button means the button is not active and touching it will have no effect.

Screen Button

Blue rectangles on the touch screen are screen buttons. By touching the blue area of the screen button the display will either change to another screen or the selection of an option will change. A screen button is not active if it is gray.

Data Box

This type of box shows selected data or data the machine is measuring. During the preventive maintenance process this type of box is used to verify a value or selection.

1.3 MEASURING FLUID VOLUMES

Several of the following procedures require measuring fluid volumes using graduated cylinders and laboratory burets. When making these measurements do the following:

- Make certain the container is clean and dry before collecting the fluid to be measured. Two drops of fluid are approximately 0.1 ml, which is enough to affect the accuracy of critical measurements.

- Ensure that no items such as thermometers or tubing are allowed to come in contact with the fluid in the graduate. Such items will change the calibration of the graduate and affect the accuracy of measurements. Both the total volume indicated and the amount of fluid indicated by each increment on the graduated scale will be incorrect. For example, if a graduate is calibrated in 1 ml increments, a piece of tubing in contact with the fluid will cause each increment to be *less* than 1 ml, depending upon the total volume of the tubing that penetrates into the fluid.

- Surface tension causes the fluid to curve into a meniscus (see Figure 1). Measure the volume at the bottom of the meniscus curve as shown.

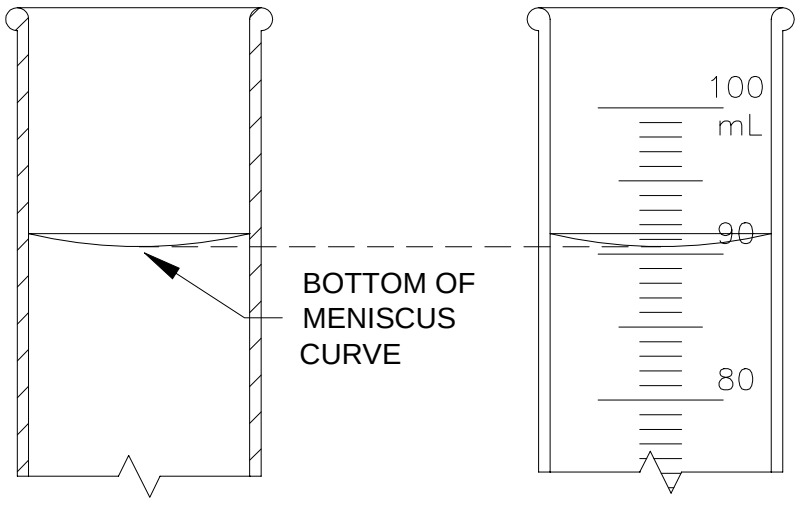

Figure 1. Meniscus Curve.

2.0 QUARTERLY (1000 HOUR) PREVENTIVE MAINTENANCE

Perform the following Preventive Maintenance procedures every 3 months or 1000 hours of machine operation, whichever comes first. Make copies of the Quarterly Preventive Maintenance Checklist provided in the back of this manual and use them to record the maintenance done.

When performing an Annual Preventive Maintenance do not perform the quarterly procedures below first. Go directly to Section 3 and perform the annual procedures described there. You will be referred back to this section to perform the quarterly procedures along with the annual procedures in the most efficient order.

While performing the following procedures, check the floor of the hydraulic unit and all surfaces for moisture that might indicate a leak. Locate and correct any leaks detected. Clean the floor of the hydraulic unit so that future leaks will be readily apparent. Also, check all electrical connectors that can be reached to be sure they are fully seated and there is no strain on the electrical cables.

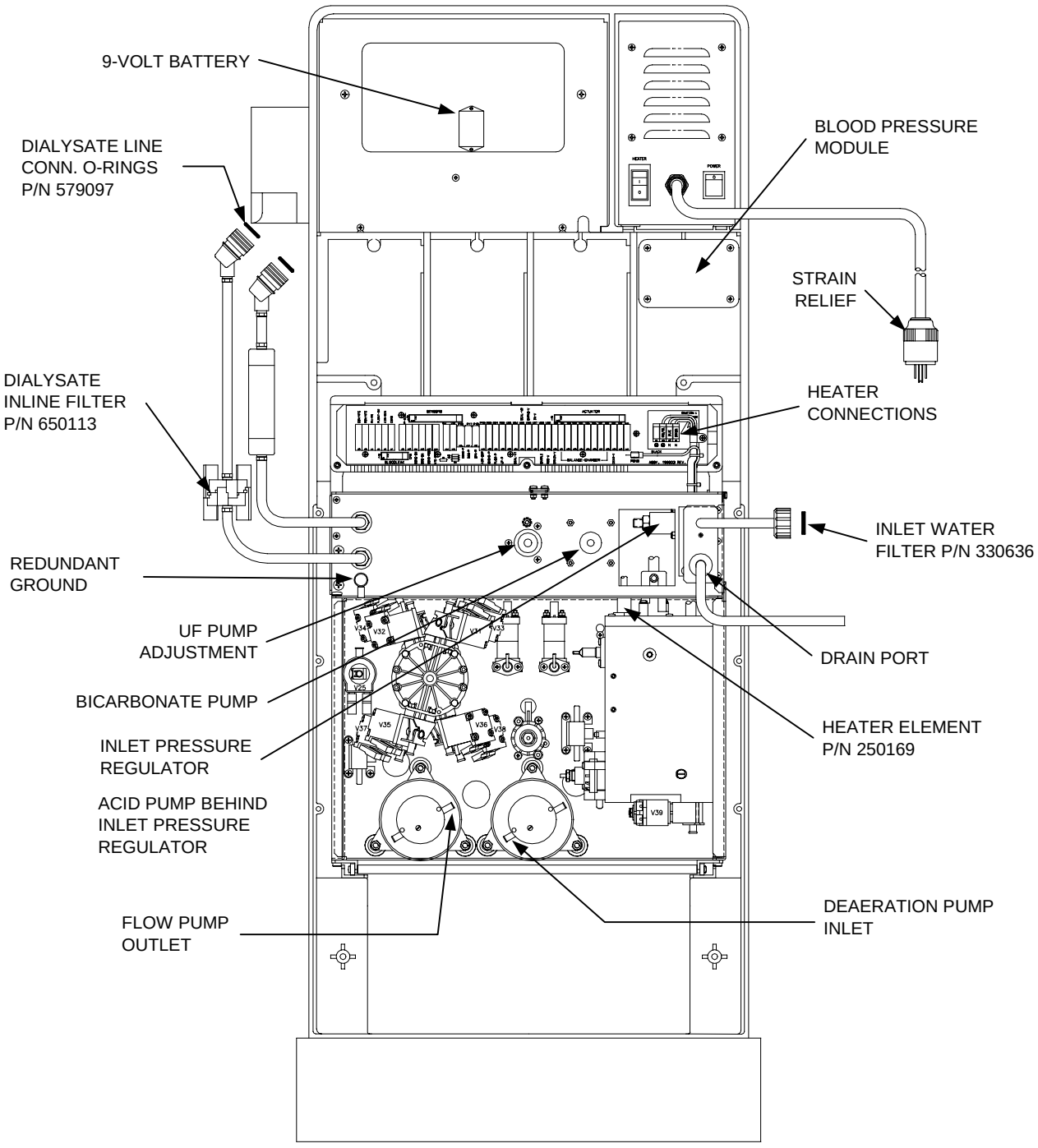

Figure 2. Fresenius 2008K Hemodialysis System, Rear View.

2.1 FILTERS AND O-RINGS

Clean filters and replace O-rings as follows. Replace any filters that appear damaged or corroded.

1. Inlet Water Filter in the inlet connector of the water supply (See Figure 2, pg. 7).

Warning! After cleaning or replacing the inlet filter screen, disinfect the water line inlet as described in the Operator's manual and in accordance with your Unit Policy.

Warning! Do not use excessive O-ring lubricant, as silicone-gel can damage the hydraulic pressure transducers (P-DIAL and CFS).

2. Filters and O-rings in the Concentrate and Bicarbonate Connectors (See Figure 3). Replace all three O-rings in each connector.

3. Dialysate Inline filter (See Figure 2, pg. 7).

4. O-rings in the Dialysate Line Connectors (See Figure 2, pg. 7).

5. Pre-UF Pump Filter. To reach this filter, remove the hydraulic unit. The filter is in the plastic housing in the input line to the UF pump. The inlet line should be the lower line entering the pump. Open the housing to remove the filter screen. If needed, the filter part number is 566307, the same as that used in the Acid and Bicarbonate filters. Replace the Pre-UF Pump Filter if the housing shows signs of leakage or distortion.

2.1A DIASAFE® FILTER (IF APPLICABLE)

If the machine is equipped with a DIASAFE® filter system, replace the DIASAFE® filter and its quick connector O-rings (P/N 579097) every 90 days (quarterly).

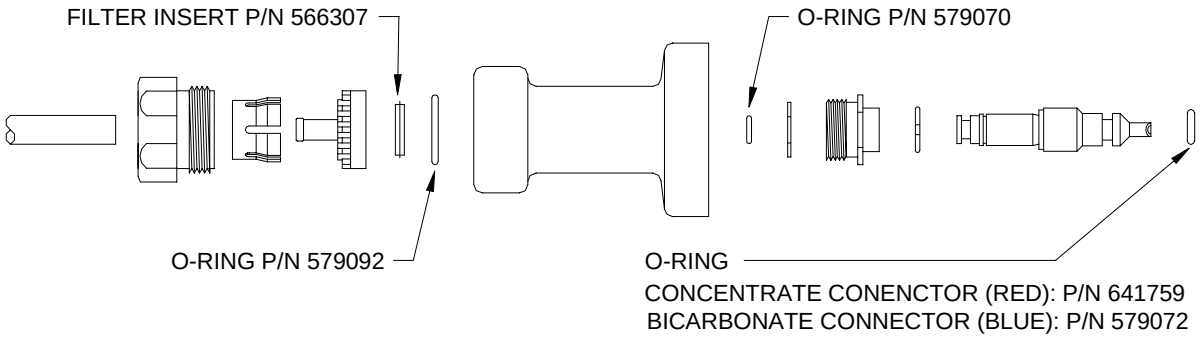

Figure 3. Concentrate and Bicarbonate Connector Assemblies.

2.2 CHECK VALVES

ANNUAL MAINTENANCE

If an Annual maintenance is being performed, replace the following check valves:

Caution: Ensure each check valve is oriented correctly to allow fluid flow in the proper direction.

1. UF Pump Output. There are two check valves at the UF pump output. One is at the UF pump itself. The other is downstream at the UF Sample Port.

2. Concentrate and Bicarbonate Pump Output (Central Feed Systems only). If the facility has a central feed system, a check valve is located at the output of the concentrate pump if the central feed system provides acid, or the bicarbonate pump if the central feed system provides bicarbonate. These valves have a white insert with a 6-pound spring (part no. 150209).

Caution: Ensure the feed pressure from the central system does not exceed 2 psi.

QUARTERLY MAINTENANCE

If a Quarterly maintenance is being performed, inspect both UF pump check valves. Also, if applicable, inspect the Central Feed System check valves. Replace any that show signs of wear or damage. Open each valve and inspect the valve body for cracks, distortion or signs of leakage. Inspect the springs to ensure they are not deformed and are seated properly. Check the poppet for proper O-ring seating.

Caution: If a check valve is replaced, ensure it is oriented correctly to allow fluid flow in the proper direction.

2.3 UF PUMP

Verify the UF pump as follows:

1. Remove the dialyzer connectors from the shunt and place them in a bucket of water on the floor.
2. Place the machine in Dialysis Mode and clear all blood alarms.
3. On the Home screen, set the UF Rate to 1000ml/hr.
4. Connect the FLUID SAMPLE/ULTRAFILTRATE output tubing to a 25 ml buret. Open the buret stopcock (See Figure 4).
5. Press the [UF on/off] key. The green light above the key should light, indicating that the UF pump is running and fluid should be pumped into the buret. If this light is flashing, there is a blood alarm or the machine is in a Fill Program and the UF Pump will not run. Correct any conditions as required so the green light does not flash.

Note: If the UF Pump does not provide output even though the green light is on and not flashing, inspect the check valves. If a check valve is installed backwards, the pump will not work.

6. Slide the hydraulic chassis out a few inches so that the UF pump is visible. While the UF pump is stroking, observe the piston and the solenoid. Look for signs of the piston sticking, or evidence of corrosion in the solenoid barrel.

Note: The solenoid is a sealed unit - no lubrication is necessary. Corroded components should be replaced as necessary.

7. When fluid appears in the buret, press the [UF on/off] key to stop the pump, then adjust the amount of fluid in the buret so the meniscus is on the 25 ml mark (See Figure 4).

8. Press the [UF on/off] key and allow exactly 24 pulses of fluid into the buret, then press the [UF on/off] key again to stop the pump.

9. Measure the amount of fluid collected. The level in the buret should be between 0.90 and 1.10 ml on the buret scale indicating that between 23.90 and 24.10 ml was collected. If the volume collected is not within this range, repeat this test to ensure it is done accurately before considering re-calibration or other repairs.

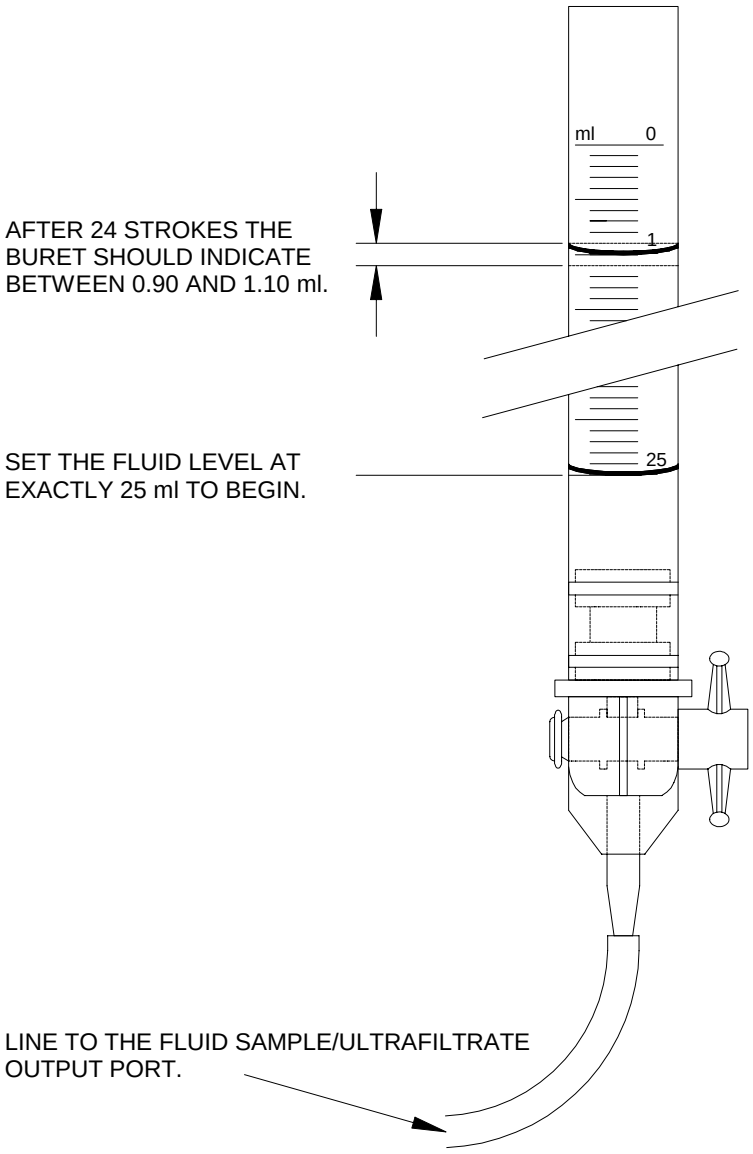

Figure 4. UF Pump Volume Measurement.

2.4 CONDUCTIVITY

Verify that the dialysate conductivity measured by the internal cell in the machine agrees with an external meter within 0.1 mS/cm as follows:

1. Connect an external conductivity meter to the dialysate lines.

2. With the machine in Dialysis Mode and flow ON, compare the value shown on the external meter with the conductivity shown on the Display screen. They must be within 0.1 mS/cm of each other.

2.5 TEMPERATURE

Verify that the actual dialysate temperature measured by an external meter agrees with the display screen within 0.5°C at 37°C and 39°C as follows:

1. Connect the dialysate lines to an external meter.

2. Place the machine in Dialysis Mode with concentrate in the system. Clear any alarms.

3. Select the Temperature button. The button label will change to Temp. Setting. The value now displayed on this button is the temperature set point. Adjust the temperature set point to exactly 37.0 then press the [CONFIRM] key. The button will change back and now reads the actual temperature of the dialysate again. Wait until this value stabilizes. It will settle very close to the value set, depending upon inlet water temperature and other conditions.

4. After the temperature of the dialysate stabilizes, compare the temperature shown on the Temperature button with the temperature shown on the external meter connected to the dialysate lines. The two readings must be within 0.5° of each other.

5. Repeat steps 3 and 4 with the temperature set to 39.0°C. Verify that the actual temperature reported on the front panel display screen and the external meter are within 0.5° of each other after the temperatures stabilize again.

2.6 ALARM AND PRESSURE HOLDING TESTS

Verify the automatic alarms produce the responses shown in Table 1 and the machine passes the automatic pressure holding test as follows:

1. Place the dialysate lines in the shunt and close the door.

2. Place a venous chamber filled with water in the holder on the level detector module.

3. Place the machine in Dialyze mode and start the blood pump. Clear all blood and water alarms.

4. Select the Test & Options button. On this screen press the Both Tests button. Press the [CONFIRM] key to start.

5. Observe the machine stepping through the following alarm tests and ensure that each alarm produces all of the responses shown in Table 1.

Table 1. Alarm Tests.

ALARM TEST	RESPONSE
Air Detector	1. Red visual alarm 2. Venous clamp closes 3. Blood pump stops
Blood Leak	1 Red visual alarm 2. Venous clamp closes 3. Blood pump stops
Arterial Pressure	1. Red visual alarm 2. Venous clamp closes 3. Blood pump stops
Venous Pressure	1. Red visual alarm 2. Venous clamp closes 3. Blood pump stops
TMP	1. Red visual alarm 2. Venous clamp closes 3. Blood pump stops
9-Volt Battery	Passes if battery voltage is greater than 7.0 volts under a load of 22Ω.
Optical Detector	1. Lower venous alarm limit rises to 0 mmHg causing a venous pressure alarm 2. Venous clamp closes 3. Blood pump stops
Temperature	1. Red visual alarm 2. Yellow visual bypass 3. Machine in Bypass mode (no flow through the dialysate flow indicator).
Conductivity	1. Red visual alarm 2. Yellow visual bypass 3. Machine in Bypass mode (no flow through the dialysate flow indicator).

6. When the tests shown in Table 1 are complete, the machine conducts a pressure holding test. When the test ends verify that the display screen reports TEST COMPLETE, indicating that all the tests were passed successfully. Press the [RESET] key.

7. Test the UF pump integrity as follows:

    - Pull the hydraulic out and remove the output tube from the UF pump.

    - Install a 24" tube (P/N 545325) to the empty output port. Route this tubing out the back of the machine so that it will not be kinked or pinched when the hydraulics is closed. Close the hydraulics and place the other end of tube into a collection container.

    - Conduct steps 1-6 again.

        - If the pressure holding test fails, refer to Section 4.1.

        - If the pressure holding test passes, disconnect the 24" tube and reconnect the original output tube to the UF pump.

8. Test the audible alarm as follows:

    - Place a piece of opaque paper inside the housing of the optical detector to simulate a line containing blood. Close the door of the optical detector.

    - Open the shunt door. Verify that the machine responds with an audible alarm. Press the [Mute] key and verify that the Mute lamp lights, and the audible tone stops.

2.7 LABELS AND MECHANICAL CONDITION

Before returning the machine to clinical use after successful completion of all of the Preventive Maintenance procedures listed above, complete the following:

- Verify that the machine label with serial number is in place, usually on the back of the cabinet near the Monitor Control Unit. Record this serial number on the Preventive Maintenance Checklist form.

- Verify that no dialysate spills or leaks are visible in the hydraulics or on the bottom of the cabinet. Clean and dry any spills found and correct the source.

- Verify that all covers are replaced and that all cover screws and mounting hardware has been replaced.

Caution: Reliable operation of the machine requires that all screws and covers be properly installed. Ensure that all screws and covers are in place before returning the machine to clinical use.

- Clean the exterior surfaces of the machine and remove all traces of dirt, oil or other contaminants.

Caution: Do not use a cleaner containing Dimethyl Benzylammonium Chloride. This ingredient will damage many plastic surfaces. Certain brands of cleaners specifically marketed to clinics and hospitals contain this ingredient. Check the contents of any unknown cleaner before using it.

3.0 ANNUAL (4000 HOUR) PREVENTIVE MAINTENANCE

Perform the following Preventive Maintenance procedures every 12 months or 4000 hours of machine operation, whichever comes first. Perform the procedures in the order given below to complete the Annual Preventive Maintenance and the Quarterly Preventive Maintenance. The following procedures will refer back to the Quarterly Preventive Maintenance procedures at the proper times for you to work in the most efficient manner.

Make copies of the Annual Preventive Maintenance Checklist provided at the back of this manual and use them to record the maintenance done.

3.1 FILTERS, O-RINGS AND CHECK VALVES

Perform the Quarterly Preventive Maintenance procedures in Sections 2.1 and 2.2.

3.2 DIAPHRAGM PUMPS

Rebuild the UF, Bicarbonate and Concentrate diaphragm pumps as described in Section 4.

3.3 HEATER ELEMENT

Remove the heater element from the hydroblock on the machine (See Figure 2, pg. 7). Inspect the heater element for signs of corrosion. If corrosion exists, replace the heater element.

⚠ **Warning!** Dangerous high voltage is present at these connections when the machine is operating. The heater element is hot enough to inflict serious injury if it is touched while power is applied or shortly after power is removed. Ensure the machine is disconnected from the wall outlet.

3.4 HIGH VOLTAGE AC CONNECTIONS

Warning! Dangerous high voltage is present at the connections accessed in this procedure when the machine is operating. Ensure the machine's power plug is disconnected from the wall outlet before proceeding.

1. Remove power from the machine then check and tighten the 8-pin heater connections next to the distribution board (See Figure 2, pg. 7).

2. Inspect the power plug for loose or frayed wires. Ensure the strain relief is securely fastened.

3. With a digital multimeter, measure the resistance between the round (ground) pin on the power plug and the redundant ground terminal on the machine (See Figure 2, pg. 7). Verify that the resistance is less than 0.2 ohm. If the value is above 0.2 ohm, measure the internal resistance of your meter by shorting the leads together, then subtract this value from the resistance measured between the power plug ground pin and the redundant ground terminal on the machine to obtain the true ground resistance.

Warning! Do not operate the machine if the resistance is greater than 0.2 ohm. A shock hazard to operators and patients could exist.

4. Perform the electrical safety checks required by local codes, facility procedure and the Joint Commission on Accreditation of Healthcare Organizations.

3.5 DEAERATION MOTOR BRUSHES

Replace the deaeration motor brushes every 8000hrs using the following steps:

1. Remove the complete deaeration motor/pump assembly from the machine.

2. Using a marker, make hatch marks on the motor housing and motor cap as illustrated below. These marks will ensure the correct alignment when reassembling the motor case.

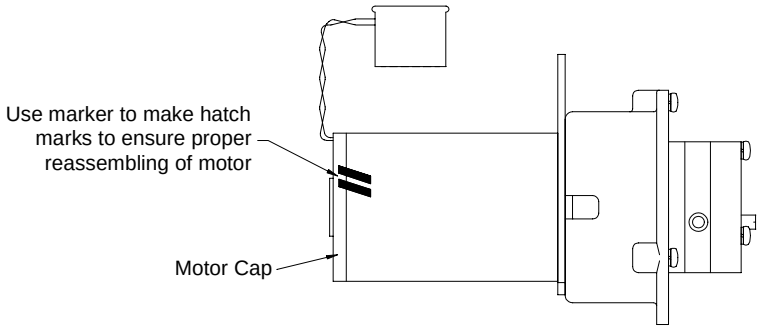

Figure 5. Deaeration Motor with hatch marks.

3. Using a T-20 Torx screwdriver, remove the two screws holder the motor cap to the motor housing.

4. Remove the motor cap to gain access to the motor brushes. Replace the motor brushes.

5. Reassemble the motor, aligning the hatch marks.

6. While holding the pieces together, install and tighten the two T-20 screws.

Note: If the motor case and motor cap are not installed using the hatch marks, the motor will run in reverse and flow errors will result.

3.6 INLET WATER PRESSURE REGULATOR

Verify that the regulator provides the proper water pressure as follows:

1. Turn off the dialysate flow.
2. Shut off the water supply to the machine.
3. Install a gauge with a T-fitting to monitor the pressure at the outlet side of the Inlet Pressure Regulator (See Figure 2, pg. 7).

Caution: Use tie wraps or tubing clamps to secure the connections. The water pressure may be sufficient to blow the lines off the fittings if they are not secured.

4. Turn the water supply to the machine ON.
5. With the dialysate lines in the shunt, select Dialysis Mode and start the dialysate flow. The pressure gauge will cycle between two readings as water inlet valve opens and closes.
6. Verify that the pressure gauge reads between 18 and 20 psi when the pressure is at its highest value, and reads greater than 8 psi when the pressure is at its lowest value.

Note: Readings below 8 psi at the lowest level indicates inadequate inlet water flow into the machine. This may be caused by a dirty inlet filter screen or problems with the treated water supply.

7. Turn the machine OFF, turn off the source water supply, remove the gauge and reconnect the tubing using clamps to prevent leaks.
8. Turn the treated water supply source ON, turn the machine ON and select Dialysis Mode. Start dialysate flow and inspect all hoses and connections. Ensure that there are no leaks.

3.7 ONLINE CLEARANCE TEST (IF APPLICABLE)

If the machine is equipped with Online Clearance (OLC), conduct the following test:

1. Turn the machine ON and allow the machine to run in Dialysis Mode at 500 ml/min flow rate.

2. The machine will automatically start the OLC Self Test by displaying a banner. When the test starts, open the shunt door. This will cancel the test.

Note: The cancel message will be hidden by the Shunt Door Open banner.

3. Close the shunt door and verify that the OLC Self Test banner is gone.

4. Once the OLC Self Test has been canceled, allow the machine to run in Dialysis Mode for approximately 10 minutes. This allows the machine to come up to temperature and conductivity.

5. Once the machine is warmed up, remove X3 (MON-NTC) and X7 (COND) from the distribution board.

6. Using the Resistor Plug Set for OLC Testing (P/N 190168), plug the 6.04KΩ plug into X3 (MON-NTC) and the 274Ω plug into X7 (COND) on the distribution board.

Note: Due to the resistor placement inside the OLC test plugs, the orientation of the plug when inserted onto the distribution board is irrelevant.

7. Switch to the debug screens by pressing and holding the [▲] and [▼] keys at the same time for approximately 1 sec. The main display will change indicating that the machine is in debug mode.

8. Use the [▲] and [▼] keys to go to debug screen #5.

9. On debug screen #5, locate TPRE and observe its value for 1 minute. During this time, record the highest and lowest values observed in the table below.

	Highest Value	Lowest Value	Difference
TPRE	-	=	

10. Calculate the difference between the highest and lowest TPRE value and record it in the table above.

11. Verify that the difference for TPRE < 2. If the difference for TPRE > 2, then possible causes are sensor board, motor noise, or -12V problems.

12. Again on debug screen #5, locate CPRE and observe its value for 1 minute. During this time record the highest and lowest values observed in the table below.

	Highest Value	Lowest Value	Difference
CPRE	-	=	

13. Calculate the difference between the highest and lowest CPRE value and record it in the table above.

14. Verify that the difference for CPRE < 8. If the difference for CPRE > 8, then possible causes are sensor board, motor noise, or -12V problems.

15. Remove the 6.04KΩ and 274Ω plug from the distribution board and replace the original connectors.

16. Remove X44 (NTC-POST) and X13 (COND-POS) from the distribution board.

17. Using the Resistor Plug Set for OLC Testing (P/N 190168), plug the 6.04KΩ plug into X44 (NTC-POST) and the 274Ω plug into X13 (COND-POS) on the distribution board.

18. On debug screen #5, locate TPOS and observe its value for 1 minute. During this time record the highest and lowest values observed in the table below.

	Highest Value	Lowest Value	Difference
TPOS	-	=	

19. Calculate the difference between the highest and lowest TPOS value and record it in the table above.

20. Verify that the difference for TPOS < 2. If the difference for TPOS > 2, then possible causes are sensor board, motor noise, or -12V problems.

21. Again on debug screen #5, locate CPOS and observe its value for 1 minute. During this time record the highest and lowest values observed in the table below.

	Highest Value	Lowest Value	Difference
CPOS	-	=	

22. Calculate the difference between the highest and lowest CPOS value and record it in the table above.

23. Verify that the difference for CPOS < 8. If the difference for CPOS > 8, then possible causes are sensor board, motor noise, or -12V problems.

24. With the 6.04KΩ plug on X44 (NTC-POST) and the 274Ω plug on X13 (COND-POS) of the distribution board, verify that CPOS does not change more then 10 increments when the dialysate flow is turned OFF. (Note: Conduct this test for the dialysate flow ON to OFF transition.)

25. Remove the 6.04KΩ and 274Ω plug from the distribution board and replace the original connectors.

26. Once the distribution board connections are back in place, turn the machine OFF.

Note: The machine must be powered OFF prior to conducting the next step. This allows the machine to automatically start the OLC Self Test.

27. Turn the machine ON and allow the machine to run in Dialysis Mode at 500 ml/min flow rate for approximately 10 minutes. This allows the machine to come up to temperature and conductivity.

28. Once the temperature and conductivity are stable, the OLC Self Test (Zero Test) will start automatically.

29. When the OLC Self Test is complete, go to debug screen #5 and confirm that 0TST is in the range ±20.

Note: If 0TST is out of range, the OLC Self Test will fail. If this happens, conduct temperature (PRE & POST) and conductivity calibrations, then conduct OLC Self Test again.

3.8 DEAERATION AND LOADING PRESSURE

Verify that the deaeration pressure is between –24 and -25 inHg and the loading pressure is between 18 and 20 psi (between 23 and 25 psi if a DIASAFE® filter system is installed) as follows:

1. With dialysate flow OFF, install a gauge with a T-fitting to monitor the pressure on the inlet (suction) side of the deaeration pump (See Figure 2, pg. 7).

2. Connect a gauge equipped with a yellow connector into the red ACETATE/ACID port.

3. In Dialysis Mode, turn dialysate flow ON and verify that the gauge on the deaeration pump indicates between -24 and -25 inHg. The needle will be vibrating somewhat. Verify that it does not go higher than -24 inHg or lower than -25 Hg. Verify that the gauge in the ACETATE/ACID port indicates between 18 and 20 psi (between 23 and 25 psi if a DIASAFE® filter system is installed).

3.9 FLOW RELIEF PRESSURE

Verify that the flow relief pressure is between 29 and 30 psi (between 35 and 36 psi if a DIASAFE® filter system is installed) as follows:

1. With dialysate flow OFF, install a gauge with a T-fitting to monitor the pressure on the output side of the flow pump (See Figure 2, pg. 7).

2. Turn ON the dialysate flow and set the flow to 800. Clamp the output tubing of the flow pump after the gauge. Verify the gauge indicates between 29 and 30 psi (between 35 and 36 psi if a DIASAFE® filter system is installed).

3.10 CONDUCTIVITY

Verify that the dialysate conductivity measured by the internal cell in the machine agrees with an external meter within 0.1 mS/cm as described in Section 2.4.

3.11 TEMPERATURE

Verify that the dialysate temperature shown on the front panel Display screen agrees with an external meter within 0.5°C at 37°C and 39°C as described in Section 2.5.

3.12 VOLT HI LO DETECT

Verify that the 5-volt supply is operating within 0.2 volts as reported on the debug screen as follows:

1. Switch to the debug screens by pressing and holding the [▲] and [▼] keys at the same time for approximately 1 sec. The main display will change indicating that the machine is in debug mode.

2. Use the [▲] and [▼] keys to go to debug screen #4.

3. Locate the 5V value on the display screen. This value must be between 4.8V and 5.2V.

Note: If the 5V value is not within limits, the problem is most likely the 12 volt supply out tolerance. Perform the Volt Hi Lo Detect calibration procedure.

3.13 BLOOD LEAK AND DIMNESS

Verify that the blood leak level is between 4.5 and 5.2 volts and the blood dimness level is within 5.0±1.0 volts as follows:

1. Switch to the debug screens by pressing and holding the [▲] and [▼] keys at the same time for approximately 1 sec. The main display will change indicating that the machine is in debug mode.

2. Use the [▲] and [▼] keys to go to debug screen #4.

3. Locate the LEAK value on the display screen. This value must be between 4.5 and 5.2.

4. Locate the DIMN value on the display screen. This value must be between 4.0 and 6.0.

Note: If these values are outside the limits given, perform a bleach rinse to clean the glass detector tube inside the machine before considering other repairs.

3.14 ARTERIAL, VENOUS AND TRANSMEMBRANE PRESSURE

ARTERIAL PRESSURE

1. Inspect the internal pressure transducer protector for contamination. If contamination is found, replace the pressure transducer protector (P/N 650158) and remove and disinfect the pressure port with 1:100 bleach for a minimum of 15 minutes.
2. Open the arterial transducer port **P**$_{ART.}$ on the blood pump module to air (atmospheric pressure). Verify that the Arterial Pressure bargraph indicates 0.
3. Attach a syringe and a calibrated pressure gauge to the **P**$_{ART.}$ port using a T-fitting.
4. Push the syringe in to show a pressure of 200 mmHg on the external gauge. Verify that the Arterial Pressure bargraph indicates 200.
5. Increase the pressure to a range of 310 - 315mmHg. Clamp off the tubing at the syringe and monitor for 30 seconds. The maximum allowable leakage is 2mmHg in 30 seconds.

VENOUS PRESSURE

1. Inspect the internal pressure transducer protector for contamination. If contamination is found, replace the pressure transducer protector (P/N 650158) and remove and disinfect the pressure port with 1:100 bleach for a minimum of 15 minutes.
2. Open the venous transducer port **P**$_{VEN.}$ on the level detector module to air (atmospheric pressure). Verify that the Venous Pressure bargraph indicates 0.
3. Attach a syringe and a calibrated pressure gauge to the **P**$_{VEN.}$ port using a T-fitting.
4. Push the syringe plunger in to show 400 mmHg on the external pressure gauge. Verify that the Venous Pressure bargraph indicates 400.
5. Decrease the pressure to a range of 310 - 315mmHg. Clamp off the tubing at the syringe and monitor for 30 seconds. The maximum allowable leakage is 2mmHg in 30 seconds.

TRANSMEMBRANE PRESSURE

1. With dialysate flow ON, ensure the dialysate lines are full of fluid and no air is visible passing through the flow indicator.
2. Hang a four-way connector to the I.V. pole at normal dialyzer height.
3. Set dialysate flow to 500 ml/min, then press the [CONFIRM] key.
4. Turn dialysate flow OFF, remove the dialysate lines from the shunt and attach them to the connector.

Note: Filling the lines before removing them from the shunt will avoid wetting the pressure gauge transducer during the test.

5. Connect a 30cc syringe to one of the four-way connector outlets and a pressure gauge to the remaining outlet.
6. Switch to the debug screens by pressing and holding the [▲] and [▼] keys at the same time for approximately 1 sec. The main display will change indicating that the machine is in debug mode.
7. Use the [▲] and [▼] keys to go to debug screen #1.
8. Use the syringe to set the pressure on the external gauge to 0 mmHg. Calculate the dialysate pressure measured by the machine as follows:
   - Note the value shown for TMP on the display screen.
   - Subtract the value shown for VEN on the display screen.
9. Verify that the calculated value is between +20 and -10 mmHg.
10. Use the syringe to create a pressure of -250 mmHg on the pressure gauge.
11. Calculate the dialysate pressure measured by the machine again as described in step 16. Verify that the calculated value is between -230 and -260 mmHg.

3.15 DIALYSATE FLOW

Verify the dialysate flow is within ±3% of the stated rate at 500 ml/min as follows:

Note: All flow rates are controlled by the software. Testing the rate at 500 ml/min verifies the accuracy of all rates.

1. In Dialysis Mode, turn the dialysate flow ON at 500 ml/min. Verify that the UF pump is OFF and the machine is out of bypass. Allow the dialysate flow to run for 2 minutes, minimum, before continuing.

2. Collect spent dialysate from the drain port on the back of the machine (See Figure 2, pg. 7) for exactly 1 minute. Verify that the amount collected is between 485 and 515 ml.

3.16 HEPARIN PUMP

If the machine is equipped with a heparin pump module, clean and test the pump as follows:

1. Place the machine in Dialysis Mode and clear all alarms.

2. Select the Heparin screen button. On this screen press the Syringe button. Use the [▲] and [▼] keys to select the syringe being used for this test and press the [CONFIRM] key.

3. Press the Load Syringe button. Press the [CONFIRM] key and the carriage will fully retract downward.

4. When the carriage has stopped, press the [Escape] key and clean the carriage bar (see Figure 6).

5. Extend the syringe plunger past the 10ml mark. Install the syringe into the pump and latch the plunger handle into the carriage. If needed, squeeze the carriage/plunger release lever to slide the carriage up to meet the plunger handle. The syringe plunger should be at a position greater than 10ml.

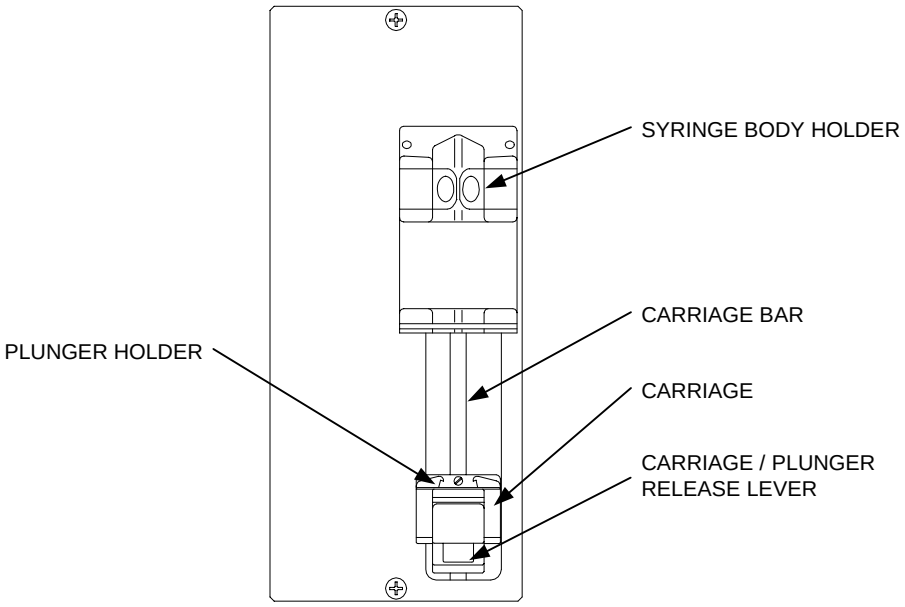

Figure 6. Heparin Pump Module.

6. Press the Heparin Prime button. Press and hold the [CONFIRM] key. The plunger will start moving towards the 10ml mark. Release the [CONFIRM] key as soon as the syringe plunger is aligned exactly with the 10ml mark on the side of the syringe body.

7. Select the Bolus data button. Use the [▲] and [▼] keys to set a value of 5.0 ml then press the [CONFIRM] key.

8. Select the Total Infused data button. Press the 0 (zero) key and then the [CONFIRM] key.

9. Press the Infuse Bolus button. Press the [CONFIRM] key and start timing the interval with the stopwatch.

10. When the pump stops, verify that the time to run a 5ml Bolus was between 29 and 30 seconds.

11. Also, verify that the Total Infused data button reads 5.0 and that the syringe plunger has moved to between 4.8 to 5.2 on the syringe scale.

12. Move the carriage all the way up to the end of its travel.

13. Select the RATE data button. Use the [▲] and [▼] keys to set a value of 9.9 ml/hr then press the [CONFIRM] key.

14. Press the [Heparin on/off] key to start the pump. The green lamp above the key should light.

15. Verify that a HEPARIN PUMP ALARM is displayed on the status line within 2 minutes.

Note: If the machine is not alarm free, another message of higher priority may be displayed on the status line.

3.17 BLOOD PUMP

Clean and test the arterial blood pump module as follows:

1. Remove the blood pump rotor by opening the door, pulling out the handle and turning the rotor 90 degrees

2. Clean the rollers with a cloth dampened only with water.

3. Clean the inside of the blood pump housing with the damp cloth. Compressed air may be used if it is available.

4. Remove the blood pump module from the machine and inspect the motor gearbox. In heavy use, some oil may accumulate on the gearbox housing. Wipe the housing clean.

5. Reassemble the blood pump module and replace it in the machine.

6. Place the machine in Dialysis Mode and clear all blood alarms.

7. Start the blood pump if it is not already running.

8. Open the blood pump door. Verify that the red alarm light on the blood pump module lights within 15 or 30 seconds.

Note: Delay time before the blood pump alarm lights is set by dipswitch 4 on the LP955 blood pump board.

9. Close the blood pump door and press the [RESET] key to clear the alarm.

3.18 LEVEL DETECTOR

1. Place a venous line in the occlusion clamp. Do not connect this line to the venous chamber in the level detector.

2. Place the lower end of the venous line below the occlusion clamp in a container of water positioned so that air escaping from the end of the line is easily seen.

3. Connect a syringe and a pressure gauge to the venous line above the occlusion clamp.

4. Position the Level Detector so you can watch the Channel 1 and Channel 2 LED's on the circuit board (See Figure 7).

5. Place the machine in Dialysis Mode and turn the blood pump ON. Clear all alarms.

6. Connect a voltmeter ground lead to TP3 (ground) on the LP450 board (See Figure 7). Measure the voltage on the solder side of pins 1 and 2 of X4 on the LP1026 relay board (See Figure 7). Verify that both pins are +24 volts.

7. Calibrate level detector (Refer to Section 3.2 of the 2008K Calibration Procedures – Fresenius part number 507296).

8. While watching the Channel 1 and Channel 2 LED's, remove the venous chamber to create a blood alarm and close the venous clamp. Verify that the Channel 1 LED lights first followed quickly by Channel 2.

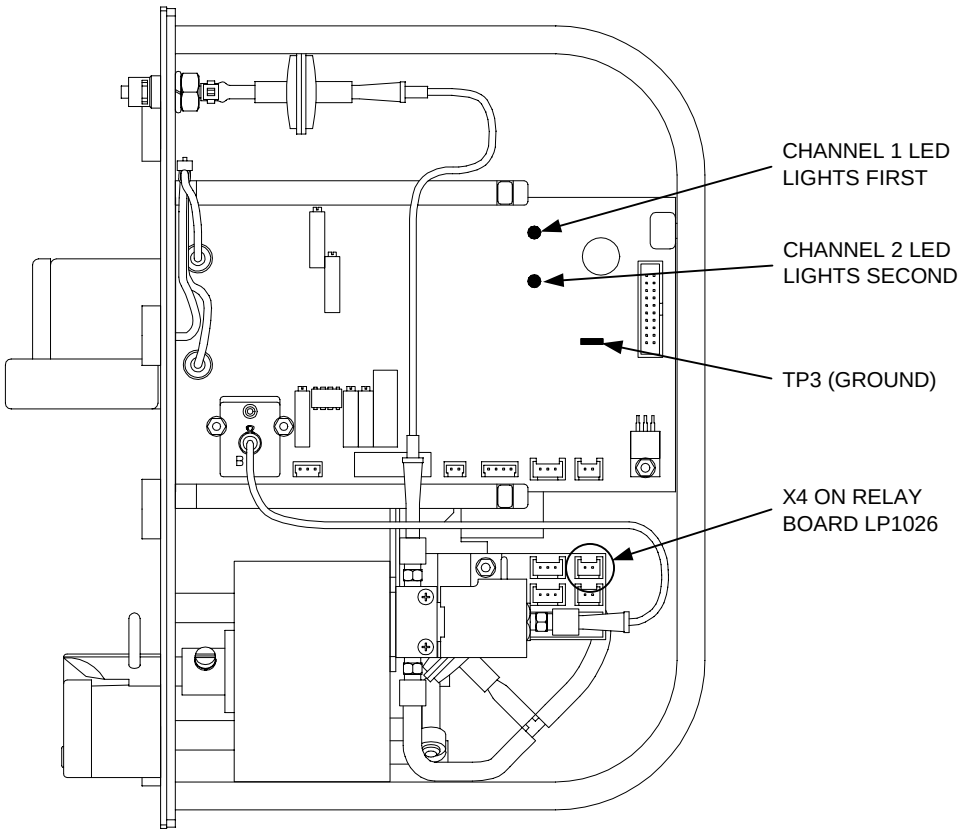

Figure 7. Level Detector Module.

9. With the ground lead of the voltmeter still attached to TP3 (ground) on the LP450 board (See Figure 7), measure the voltage on the solder side of pins 1 and 2 of X4 on the LP1026 relay board (See Figure 7). Verify that both pins are 0 volts.

10. With the syringe, apply a pressure of between at least 30 psi (1550 mmHg) to the venous line while watching the end of the venous line in the water.

11. Verify that no air escapes from the venous line, indicating that the clamp is fully occluding the line.

3.19 ALARM AND PRESSURE HOLDING TESTS

Perform the Quarterly Preventive Maintenance procedures in Section 2.6.

3.20 RINSE CHECKS

Perform the Rinse Checks as follows:

1. Place the machine in rinse mode, then turn the water supply off. Verify that the display screen shows NO WATER.

2. Start rinse mode, and watch the flow from the drain line. The water from the drain line will stop at one point for 15 seconds. At this time put the drain line in a 1000ml graduated cylinder. Start timing when the flow starts again. At 30 seconds, remove the line from the graduated cylinder. Verify that a minimum of 310ml is collected.

3. Connect the dialysate lines to an external meter capable of reading at least 85°C. Press the Heat Disinfect button on the startup screen. The machine normally will not run in heat disinfect mode with the dialysate lines off the shunt. Start the machine in heat disinfect mode with the dialysate lines on the external meter as follows:

   - Leave the shunt door open.
   - Reach up into the opening at the bottom of the shunt and find the two spring-loaded switches that normally protrude through the holes next to the connectors when the door is closed. Push these switches in with your fingers, simulating dialysate lines connected to the shunt.
   - While holding these switches pushed in, press the [CONFIRM] key on the front panel to start the heat disinfect mode, then let go of the switches inside the shunt. Leave the shunt door open; closing it will stop the heat disinfect mode.

Warning! Scalding hot water is passing through the dialysate lines and the external meter manifold. Allow the dialysate lines and the external meter manifold to cool before disconnecting the lines.

4. The heat disinfect timer will not be operating. It is not needed. Monitor the external temperature meter and verify that the temperature rises to between 80°C and 90°C.

3.21 BATTERY AND POWER FAILURE ALARM

Replace the 9-volt battery located behind the monitor unit (See Figure 2, pg. 7). The battery is inside the plastic housing. Press the cover in and to the left to release it, then pull it out.

After replacing the battery, test the power failure alarm by removing the machine power plug from the wall outlet. Verify that the audible alarm sounds.

3.22 BLOOD PRESSURE MODULE

Test the blood pressure module (See Figure 2, pg. 7), as follows:

Place the machine in Service Mode.

Select the Test BP Module button and the screen will change.

INFLATION SPEED TEST

From the Test BP Module screen, select the Inflation Speed button.

1. Connect the pressure tubing from the module to the 700ml port on the Test Device. Ensure the tubing fits snugly on the ports.
2. Press the [CONFIRM] key. The screen will change and the test will start.
3. When the test is complete, the test results will be displayed. Verify the test results passed then press the [CONFIRM] key.

DEFLATION SPEED TEST

From the Test BP Module screen, select the Deflation Speed button.

1. Connect the pressure tubing from the module to the 220ml port on the Test Device. Ensure the tubing fits snugly on the ports.
2. Press the [CONFIRM] key. The screen will change and the test will start.
3. Wait for the test to complete. When complete the screen will change.
4. When the test is complete, the test results will be displayed. Verify the test results passed then press the [CONFIRM] key.

AIR LEAKAGE TEST

From the Test BP Module screen, select the Air Leakage button.

1. Connect the pressure tubing from the module to the 700ml port on the Test Device. Ensure the tubing fits snugly on the ports.

2. Press the [CONFIRM] key. The screen will change and the test will start.

3. Wait for the test to complete. When complete the screen will change.

4. When the test is complete, the test results will be displayed. Verify the test results passed then press the [CONFIRM] key.

CALIBRATION CHECK

From the Test BP Module screen, select the Calibrate Mode button.

1. Disconnect the pressure tube from the Test Device and connect it to a mercury manometer or similar pressure meter accurate to within 1 mmHg.

2. Press the [CONFIRM] key. The screen will change and the blood pressure module will pressurize the line.

3. When the pressure shown on the display screen an on the external meter stabilizes, verify that they agree within 3mmHg.

Caution: Do not exceed 330 mmHg in the following step. The blood pressure module may be damaged if this pressure is exceeded.

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4. Remove the hose from the external meter and connect it to a large syringe (60 cc) that has its plunger pulled back. Use the syringe to over-pressurize the blood test module while watching the display carefully. Verify that at between 320 and 330 mmHg indicated on the display screen, the pressure is automatically released.

3.23 FINAL CHECKS

1. Check the machine for any optional components that are not included here. Perform the preventive maintenance tests provided with those units.

2. Check the labels, mechanical condition and clean the machine as described in Section 2.7.

4.0 REBUILDING THE DIAPHRAGM PUMPS

The machine contains two types of diaphragm pumps. The ultrafiltration (UF) pump is a solenoid coil type. The concentrate and bicarbonate pumps are stepper motor types.

4.1 REBUILDING THE ULTRAFILTRATION PUMP

Figure 8 shows an exploded view of the ultrafiltration pump. When working on the pump, be especially careful to do the following:

- Do not lose the wear button or the shim washers inside the pump solenoid.
- Count the shim washers when you disassemble the pump. The number of washers varies as needed to mate the solenoid to the pump properly.

Caution: Replace exactly the same number of shims in the ultrafiltration pump as were removed. The pump will not operate correctly if the same number of shims are not replaced.

Examine all components for signs of corrosion. Replace any components that show signs of excessive rust.

Note: If the UF pump does not provide output even though the green light is on and not flashing, inspect the check valves. If a check valve is installed backwards, the pump will not work.

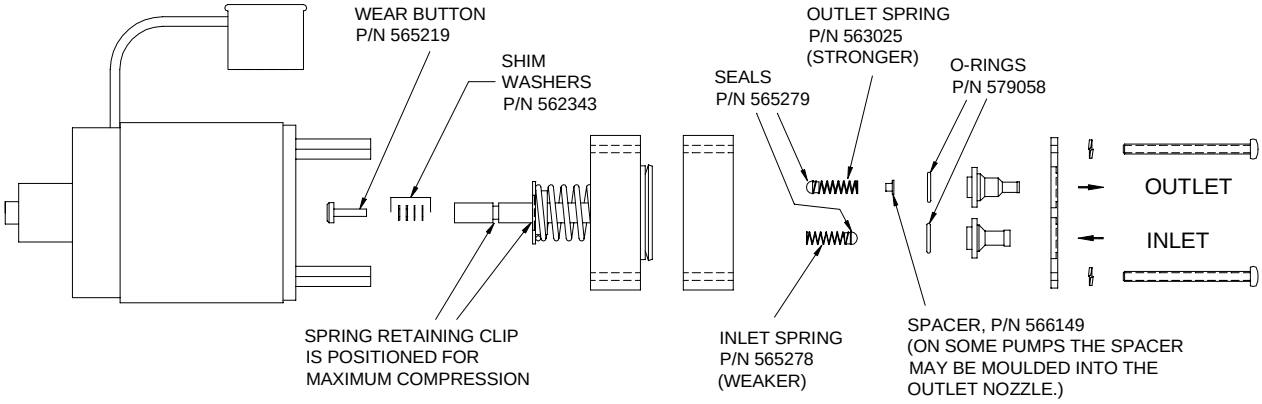


Figure 8. Ultrafiltration Pump Exploded View.

Rebuild the ultrafiltration pump as follows:

1. Remove the UF pump from the machine (See Figure 2, pg. 7). Make a note of which line goes to which port on the pump. When looking at the end plate, the arrow pointing into the pump nozzle is the input side. The arrow pointing away from the pump nozzle is the output side.

2. Hold the two sections of the pump housing and end plate together with one hand and remove the four long screws from the end plate.

3. Carefully remove the end plate to reveal the input and output nozzles, springs, seals and O-rings.

4. Replace the inlet and outlet springs.

Caution: Be certain the correct springs are used. The weaker spring goes on the inlet side. The stronger spring goes on the outlet side.

5. Inspect the seals. Replace them if there is any sign of swelling or wear.

6. Inspect the O-rings. Replace them if there is any sign of wear.

7. Reassemble the pump as follows:

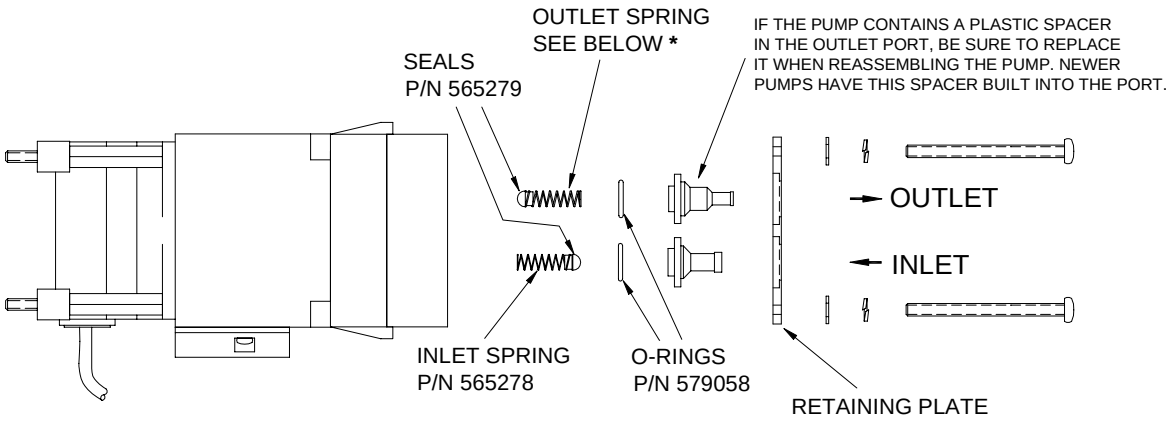
    - The outlet seal goes toward the pump membrane.
    - The inlet seal faces away from the pump membrane.
    - Reinstall the spacer in the outlet nozzle if one was removed from the pump.
    - Ensure the outlet nozzle is oriented so it will be at the top of the pump solenoid to help avoid air locks in the pump.

8. Replace the long screws into the end plate and tighten.

9. Replace the pump in the machine and reconnect the electrical and hydraulic lines. Orient the pump so the outlet nozzle is above the inlet nozzle to help avoid air locks.

4.2 REBUILDING THE CONCENTRATE AND BICARBONATE PUMPS

Figure 9 is an exploded view of the concentrate and bicarbonate pumps.



* ON CONCENTRATE (ACID) PUMPS THIS SPRING IS STRONGER THAN THE INLET SPRING. USE P/N 563025. ON BICARBONATE PUMPS USE WEAK SPRINGS FOR BOTH INLET AND OUTLET (P/N 565278).

ON MACHINES WITH ONLINE CLEARANCE (OLC), THE CONCENTRATE (ACID) PUMP USES WEAK SPRINGS FOR BOTH INLET AND OUTLET (P/N 565278).

Figure 9. Concentrate and Bicarbonate Pump Exploded View.

Rebuild the concentrate pumps as follows:

1. Remove the pump from the machine (See Figure 2, pg. 7). Make a note of which line goes to which port on the pump. When looking at the end plate, the arrow pointing into the pump nozzle is the input side. The arrow pointing away from the pump nozzle is the output side.

2. Hold the two sections of the pump housing and end plate together with one hand and remove the long screws that hold the end plate. On some models of the pump, all four screws hold the end plate, and on others only two screws hold the end plate.

   If you removed all four screws to free the end plate, replace one or two of them to avoid having the pump come completely apart. You only need access to the inlet seals and springs.

3. Carefully remove the end plate to reveal the input and output nozzles, springs, seals and O-rings.

4. Replace the inlet and outlet springs.

Caution: Be certain the correct springs are used on concentrate pumps. See Figure 9 on previous page.

5. Inspect the seals. Replace them if there is any sign of swelling or wear.

6. Inspect the O-rings. Replace them if there is any sign of wear.

7. Reassemble the pump as follows:

   - The outlet seal goes toward the pump membrane.
   - The inlet seal faces away from the pump membrane.
   - Reinstall the spacer in the outlet nozzle if one was removed from the pump.
   - Ensure the outlet nozzle is oriented so it will be at the top of the pump solenoid to help avoid air locks in the pump.

8. Replace the long screws into the end plate and tighten.

9. Replace the pump in the machine and reconnect the electrical and hydraulic lines. Orient the pump so the outlet nozzle is above the inlet nozzle to help avoid air locks.

4.3 TESTING CONCENTRATE AND BICARBONATE PUMPS

The concentrate (acid) and bicarbonate pumps are tested by measuring the volume of water they pump and comparing that measurement with the expected value determined by the machine. The measured pump volume must be within 2% of the expected value.

Test each pump as follows:

1. Place the machine in Dialysis Mode and clear all alarms.

2. Switch to the debug screens by pressing and holding the [▲] and [▼] keys at the same time for approximately 1 sec. The main display will change indicating that the machine is in debug mode.

3. Use the [▲] and [▼] keys to go to debug screen #1.

4. If you are using a bicarbonate pump and your display shows zero for the Bicarbonate Pump Volume (BMIN and BMAX), the machine is set up for a concentrate family that does not use bicarbonate. Change the concentrate selection for one requiring bicarbonate and return to this test step.

Note: Certain types of Bicarbonate or higher Bicarbonate levels selected will require the pump to double stroke. (Double stroke of the Bicarbonate pump can be checked by going to debug screen #1 and look at DOUBLE. If there is a 1 the pump is double stroking.)

Note: The AMIN, AMAX, BMIN, BMAX are the expected limits for twenty pulses of the acid (concentrate) pump volume and the bicarbonate pump volume, respectively. These volumes are based on the measured volume of the balancing chamber to produce the correct mixing ratio.

5. Connect a 25 ml buret filled with water to the concentrate connector for the pump to be tested. Use a short length of tubing forced over the end of the connector, and make sure there are no leaks in the fitting to the connector or to the buret.

6. With the machine in Dialysis Mode, press the [Dialysate Flow on/off] key to start the flow. Observe that liquid is drawn from the buret in discrete steps. Allow the machine to run and pump fluid from the buret for about 20 strokes, to prime the pump.

Note: Do not let the buret run dry so that air can enter the system.

7. Refill the buret exactly to the full mark. Press the [Dialysate Flow on/off] key to start the flow and count exactly 20 pulses of water drawn from the buret, then stop the flow.

Note: If DOUBLE=1 on debug screen #1 then count each pulse of the double stroking bicarbonate pump.

8. Measure the amount of water drawn from the buret carefully to within 0.05 ml (within 1/2 division on a buret calibrated in 0.1 ml increments). Verify that this value is between the displayed limits of AMIN and AMAX for the acid pump volume and BMIN and BMAX for the bicarbonate pump volume.

9. If a pump volume falls outside of the permitted error, repeat the above procedure to ensure that you are getting consistent results before re-calibrating the machine.

NOTES:

PREVENTIVE MAINTENANCE CHECKLIST QUARTERLY/1000 HOUR

SERIAL NO. _____ **DATE** _____

MACHINE I.D. NO. _____ **MACHINE HOURS**_____

TECHNICIAN(S) _____ **LABOR HOURS** _____

See the Referenced Section of the Fresenius 2008K Preventive Maintenance Procedures (P/N 507297 Rev A or later) for detailed instructions to perform the following:

Ref. Section	Procedure	Completed By:
2.1	**Clean Filters (replace if necessary) and replace O-Rings:**	
	Water Inlet	_____
	Acid and Bicarbonate Connectors	_____
	Dialysate Inline Filter	_____
	Dialysate Line Connectors	_____
	Pre-UF Pump	_____
2.1A	**Replace DIASAFE® filter (If Applicable)**	_____
2.2	**Inspect Check Valves (replace if necessary)**	_____
	UF Pump Output (2 valves)	_____
	Concentrate and Bicarbonate Pump Output (if central feed)	_____
2.3	**Check UF Pump**	_____
2.4	**Check Conductivity with External Meter**	_____
2.5	**Check Temperature with External Meter**	_____
3.18	**Check and Calibrate Level Detector**	_____
2.6	**Check Alarm Operation and Pressure Holding Test**	_____
2.7	**Check Labels and Mechanical Condition**	_____

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PREVENTIVE MAINTENANCE CHECKLIST
ANNUAL/4000 HOUR

SERIAL NO. _____ **DATE** _____

MACHINE I.D. NO. _____ **MACHINE HOURS**_____

TECHNICIAN(S) _____ **LABOR HOURS** _____

See the Referenced Section of the Fresenius 2008K Preventive Maintenance Procedures (P/N 507297 Rev A or later) for detailed instructions to perform the following:

Ref. Section	Procedure	Completed By:
3.1	Clean Filters, Replace O-Rings and Check Valves	_____
2.1A	Replace DIASAFE® filter (If Applicable)	_____
3.2	Rebuild UF, Concentrate and Bicarbonate Pumps	_____
3.3	Check Heater Element	_____
3.4	Check High Voltage AC Connections	_____
3.5	Replace Deaeration Motor Brushes (every 8000hrs)	_____
3.6	Check Inlet Water Pressure Regulator	_____
3.7	Conduct Online Clearance Test (If Applicable)	_____
3.8	Check Deaeration and Loading Pressure	_____
3.9	Check Flow Relief Pressure	_____
4.3	Test Concentrate and Bicarbonate Pumps	_____
2.3	Test UF Pump	_____
3.10	Check Conductivity Calibration	_____
3.11	Check Temperature Calibration	_____
3.12	Check Volt Hi Lo Detect	_____
3.13	Check Blood Leak and Dimness Calibration	_____
3.14	Check Arterial, Venous and TMP Calibration	_____
3.15	Check Dialysate Flow	_____
3.16	Check Heparin Pump (If Present)	_____
3.17	Check Blood Pump	_____
3.18	Check and Calibrate Level Detector	_____
3.19	Check Alarm and Pressure Holding Tests	_____
3.20	Rinse Checks	_____
3.21	Check Battery and Power Failure Alarm	_____
3.22	Check Blood Pressure Module	_____
3.23	Final Checks	_____

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COMMON CONVERSIONS

PRESSURE

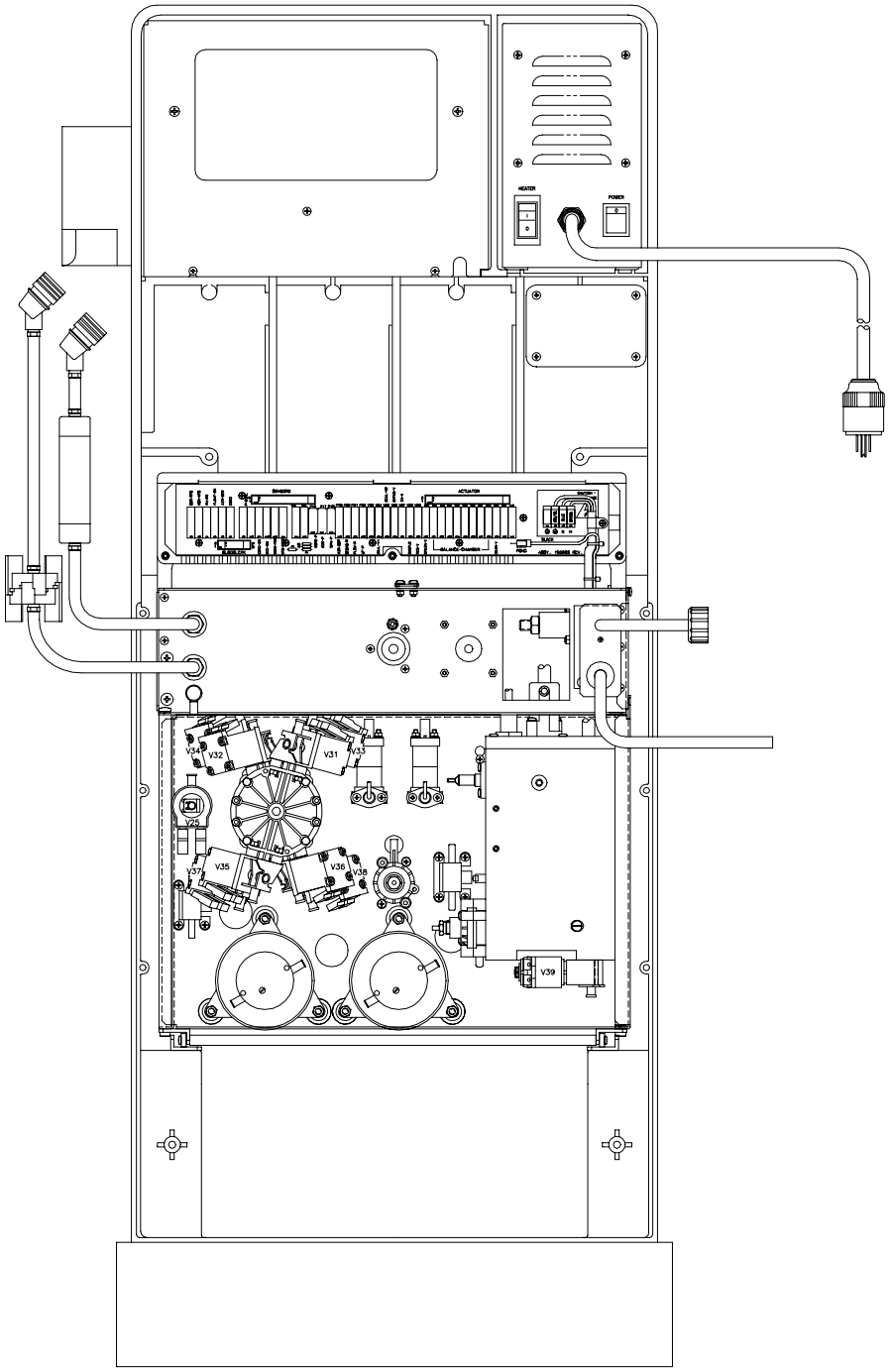
1 Bar	29.53 inHg
1 inHg	25.4 mmHg
1 Psi	51.72 mmHg

VOLUME

1 FLUID OUNCE	26.6 MILLILITERS
1 U.S QUART	0.946 LITERS
1 U.S. GALLON	3.8 LITERS
0.034 FLUID OUNCES	1 MILLILITER
1.057 QUARTS	1 LITER
0.26 U.S. GALLON	1 LITER

MASS

1 OUNCE (avdp.)	28.35 GRAMS
1 POUND (avdp.)	0.45 KILOGRAM
0.035 OUNCE (avdp.)	1 GRAM



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